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.

Subcutaneous Immune Globulin Infusion 10% (Human) with Recombinant Human Hyaluronidase (HyQvia) Infusion Clinical Guideline for Home Intravenous Therapy

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

Subcutaneous Immune Globulin Infusion 10% (Human) with Recombinant Human Hyaluronidase is an Immune Globulin Infusion 10% (Human) with a Recombinant Human Hyaluronidase, indicated for the treatment of primary immunodeficiencies in adults, including conditions such as Common Variable Immunodeficiency (CVID), X-Linked Agammaglobulinemia, Severe Combined Immunodeficiencies (SCID) and Chronic Inflammatory Demyelinating Polyneuritis (CIDP). The therapy is used to restore immune function in patients with these conditions by providing subcutaneous immunoglobulin replacement, which is facilitated by recombinant hyaluronidase to enhance absorption. The following outlines the procedures for servicing patients in need of outpatient subcutaneous Immune Globulin infusion 10% (Human) with recombinant human hyaluronidase 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. Physician orders for subcutaneous Immune Globulin infusion 10% (Human) with recombinant human hyaluronidase must include:

1. Patient weight
2. Drug
3. Dose
4. Route of administration
5. Frequency of administration

6. Emergency medications per protocol
7. Orders for pre-medications if applicable
8. Routine lab monitoring, if applicable

D. Venous access must be adequate for administration.

E. Baseline labs or tests prior to starting therapy; IgA level strongly encouraged.

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

III. PHARMACOLOGY OVERVIEW

A. Indications:

1. Primary Immunodeficiency (PI)
2. Chronic Inflammatory Demyelinating Polyneuropathy (CIDP)

B. Dosing:

1. Primary Immunodeficiency (PI)

a. For patients switching from another IgG treatment, administer the first dose one week after the previous infusion and gradually increase the dose and frequency from a 1-week dose to a 3- or 4-week dose, as per the ramp-up schedule below.

Table 1: Initial Treatment Interval/Dosage Ramp-Up Schedule

Week	Infusion Number	Dose Interval	Example for 30 grams per 4 weeks
1	1st infusion	1-week-dose	7.5 grams
2	2nd infusion	2-week-dose	15 grams
3	No infusion	Not Applicable (NA)	NA
4	3rd infusion	3-week-dose	22.5 grams
5	No infusion	NA	NA
6	No infusion	NA	NA
7	4th infusion (if required)	4-week-dose	30 grams

b. For patients transitioning from Immune Globulin Intravenous (Human) [IVIG] treatment:

i. Administer subcutaneous Immune Globulin infusion 10% (Human) with recombinant human hyaluronidase at the same dose and frequency as the previous intravenous treatment, following the initial dose ramp-up.

c. For patients at risk of measles exposure:

i. If a patient has been exposed to measles, it is recommended to administer a dose

of subcutaneous Immune Globulin infusion 10% (Human) with recombinant human hyaluronidase as soon as possible and within 6 days of exposure. A 400 mg/kg dose should achieve a serum level greater than 240 mIU/mL of measles antibodies for at least two weeks.

d. For patients at risk of future measles exposure and receiving a dose of less than 530 mg/kg every 3 to 4 weeks

    i. Increase dose to at least 530 mg/kg to ensure a serum level of 240 mIU/mL of measles antibodies for at least 22 days after the infusion.

e. For patients naive to Immune Globulin (Human) treatment or switching from SCIG treatment:

    i. Administer subcutaneous Immune Globulin infusion 10% (Human) with recombinant human hyaluronidase at 300 to 600 mg/kg at 3 to 4-week intervals, after initial ramp-up in chart above.

2. Chronic Inflammatory Demyelinating Polyneuropathy (CIDP)

a. For patients switching from Immune Globulin Intravenous (IVIG) treatment, ensure they are on stable IGIV doses before starting subcutaneous Immune Globulin infusion 10% (Human) with recombinant human hyaluronidase.
b. Calculate the weekly equivalent dose by dividing the last IGIV dose by the dosing interval.
c. The starting dose and frequency of subcutaneous Immune Globulin infusion 10% (Human) with recombinant human hyaluronidase will align with the previous IGIV treatment, typically with a 4-week dosing interval. If the previous dosing frequency was longer than 4 weeks, the interval can be adjusted to 3 or 4 weeks while maintaining the same monthly IgG dose.
d. Administer the first subcutaneous Immune Globulin infusion 10% (Human) with recombinant human hyaluronidase dose two weeks after the last IGIV infusion, followed by a second dose one week later. A ramp-up period may take up to 9 weeks, depending on the interval and patient tolerance. See example below:

Table 2: IGIV to subcutaneous Immune Globulin infusion 10% (Human) with recombinant human hyaluronidase (Hyqvia) Infusion Dose Ramp-up Schedule in Study 1

Week (Since last IV dose)	Infusion Number	Dose Interval	Example for 100 g every 4 weeks
1	No infusion	Not applicable (NA)	NA
2	1st infusion	1-week-dose	25g
3	2nd infusion	1-week-dose	25g
4	3rd infusion	2-week-dose	50g
5	No infusion	NA	NA
6	4th infusion	3-week-dose	75g
7	No infusion	NA	NA
8	No infusion	NA	NA
9	5th infusion	4-week-dose	100g (Full dose reached)

e. Additional considerations for ramp up schedule

i. If a patient tolerates the first two infusions well, subsequent doses may be increased, and dose intervals may be shortened, depending on the physician's discretion and considering infusion volume and time.
ii. For doses of 0.4 g/kg or less, a ramp-up is not required if the patient tolerates the treatment.

Dosing for all indications is based off actual body weight. subcutaneous Immune Globulin infusion 10% (Human) with recombinant human hyaluronidase has not been studied in extremes of body weights.

C. Dose Adjustment:

1. In patients with renal insufficiency or risk factors for acute kidney injury (e.g., age >65, diabetes, dehydration, sepsis, nephrotoxic medications), consider using lower and more frequent dosing. Discontinue if renal function worsens.

2. Dose changes based on Ig Trough levels: Calculate the difference between the patient's serum IgG trough level during subcutaneous Immune Globulin infusion 10% (Human) with recombinant human hyaluronidase treatment and the IgG trough level during the previous intravenous treatment. Find this difference (in mg/dL) in the columns of Table 3 and the corresponding amount (in mL) by which to increase or decrease the dose based on the patient's body weight and desired change in IgG trough level. Refer to package insert for examples.

Table 3: Individualization in Volume Administered per Dosing Interval for Intended Change in IgG Trough Levels (Difference in IgG Trough Levels)

Body Weight	100 mg/dL	200 mg/dL	300 mg/dL	400 mg/dL
10 kg	3 mL	6 mL	9 mL	12 mL
20 kg	6 mL	12 mL	18 mL	24 mL
30 kg	9 mL	18 mL	27 mL	36 mL
40 kg	12mL	24 mL	36 mL	48 mL
50 kg	15 mL	30 mL	45 mL	61 mL
60 kg	18 mL	36 mL	55 mL	73 mL
70 kg	21 mL	42 mL	64 mL	85 mL
80 kg	24 mL	48 mL	73 mL	97 mL
90 kg	27 mL	55 mL	82 mL	109 mL
100 kg	30 mL	61 mL	91 mL	121 mL
110 kg	33 mL	67 mL	100 mL	133 mL
120 kg	36 mL	73 mL	109 mL	145 mL
130 kg	39 mL	79 mL	118 mL	158 mL
140 kg	42 mL	85 mL	127 mL	170 mL

Note: When administered at the same dose and frequency, serum IgG levels from subcutaneous Immune Globulin infusion 10% (Human) with recombinant human hyaluronidase should be similar to those from intravenous treatment. If subcutaneous Immune Globulin infusion 10% (Human) with recombinant human hyaluronidase is given at a different interval than the prior treatment (either intravenously or subcutaneously), Table 2 should not

be applied. In this case, adjust the subcutaneous Immune Globulin infusion 10% (Human) with recombinant human hyaluronidase dose based on the patient's clinical response.

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

E. Contraindications:

1. Patients who have had a history of anaphylactic or severe systemic reactions to the administration of IgG.
2. IgA deficient patients with antibodies to IgA and a history of hypersensitivity.
3. Patients with known systemic hypersensitivity to hyaluronidase including recombinant human Hyaluronidase of subcutaneous Immune Globulin infusion 10% (Human) with recombinant human hyaluronidase.
4. Patients with known systemic hypersensitivity to human albumin (in the hyaluronidase solution).

F. Warnings and Precautions:

1. Hypersensitivity
   Severe hypersensitivity reactions, including anaphylaxis, may occur even in patients who have previously tolerated IgG treatment. If hypersensitivity occurs, stop the subcutaneous Immune Globulin infusion 10% (Human) with recombinant human hyaluronidase infusion immediately and provide appropriate treatment. subcutaneous Immune Globulin infusion 10% (Human) with recombinant human hyaluronidase contains trace amounts of IgA (37 μg/mL on average), which may increase the risk of hypersensitivity, especially in patients with IgA antibodies.
2. Thrombosis
   Thrombosis, including venous and arterial events, has been reported with immune globulin treatments, including subcutaneous Immune Globulin infusion 10% (Human) with recombinant human hyaluronidase. Risk factors for thrombosis include advanced age, prolonged immobility, hypercoagulable conditions, history of thrombosis, use of estrogens, and other cardiovascular risk factors. Patients with conditions that may increase blood viscosity should have their viscosity assessed before starting treatment. To minimize risk, administer subcutaneous Immune Globulin infusion 10% (Human) with recombinant human hyaluronidase at the lowest effective dose and rate, and ensure adequate hydration. Monitor for signs of thrombosis and assess blood viscosity in at-risk patients.
3. Immunogenicity
   In clinical studies, 18% of patients developed non-neutralizing antibodies to recombinant human Hyaluronidase, a component of subcutaneous Immune Globulin infusion 10% (Human) with recombinant human hyaluronidase. These antibodies may cross-react with endogenous hyaluronidase (PH20), which is present in the adult male testes, but the clinical significance is unknown. In studies of Chronic Inflammatory Demyelinating Polyneuropathy (CIDP), transient increases in neutralizing antibodies were observed without any impact on efficacy or safety.
4. Aseptic Meningitis Syndrome (AMS)
   AMS has been reported with immune globulin products, including subcutaneous Immune Globulin infusion 10% (Human) with recombinant human hyaluronidase. It is more common in females and typically begins within several hours to two days after treatment. AMS symptoms include severe headache, fever, neck stiffness, photophobia, nausea, and vomiting. CSF studies often show pleocytosis and elevated protein levels. Discontinuation of treatment usually results in symptom resolution within a few days.

5. Hemolysis
   IgG products, including subcutaneous Immune Globulin infusion 10% (Human) with recombinant human hyaluronidase, contain antibodies that can cause hemolysis. Monitor for signs of hemolysis, such as anemia, jaundice, or dark urine. If hemolysis is suspected, confirm through laboratory tests.
6. Renal Dysfunction/Failure
   Acute renal failure, including conditions like acute tubular necrosis, has been associated with intravenous IgG products, although subcutaneous Immune Globulin infusion 10% (Human) with recombinant human hyaluronidase does not contain sucrose. Patients at risk for renal dysfunction, such as those with pre-existing kidney issues or conditions like diabetes, should have renal function monitored. If renal function declines, consider discontinuing subcutaneous Immune Globulin infusion 10% (Human) with recombinant human hyaluronidase.
7. Spread of Localized Infection
   Avoid infusing subcutaneous Immune Globulin infusion 10% (Human) with recombinant human hyaluronidase into or around infected areas to prevent the spread of infection.
8. Transfusion-Related Acute Lung Injury (TRALI)
   TRALI, a form of non-cardiogenic pulmonary edema, can occur after intravenous IgG infusion and has been reported with subcutaneous Immune Globulin infusion 10% (Human) with recombinant human hyaluronidase. Symptoms include severe respiratory distress, pulmonary edema, and fever, typically within 1-6 hours after infusion. Patients should be monitored for pulmonary reactions, and if TRALI is suspected, oxygen therapy and ventilatory support may be necessary.
9. Transmissible Infectious Agents
   Subcutaneous Immune Globulin infusion 10% (Human) with recombinant human hyaluronidase is made from human plasma and may carry a risk of transmitting infectious agents, e.g., viruses, the variant Creutzfeldt-Jakob disease (vCJD) agent and, theoretically, the Creutzfeldt-Jakob disease (CJD). No cases of viral transmission or vCJD have been reported with subcutaneous Immune Globulin infusion 10% (Human) with recombinant human hyaluronidase, but all suspected infections should be reported to Takeda Pharmaceuticals.
10. Interference with Laboratory Tests
    Infusions of immune globulin products, including subcutaneous Immune Globulin infusion 10% (Human) with recombinant human hyaluronidase, can lead to false-positive results in serological tests, such as the Coombs' test or ß-D-glucan assays for fungal infections, due to the presence of passively transferred antibodies. These effects may persist for weeks after infusion.
11. Pregnancy and lactation
    Subcutaneous Immune Globulin infusion 10% (Human) with recombinant human hyaluronidase should only be used during pregnancy if absolutely necessary, as limited data on its effects are available. A small study found two infants with congenital abnormalities, though animal studies showed no teratogenic effects. The impact of subcutaneous Immune Globulin infusion 10% (Human) with recombinant human hyaluronidase on fetal development or reproductive capacity is unknown. In lactating women, the effects on breastfed infants are unclear, although animal studies suggest no significant harm. One of the components, recombinant human Hyaluronidase, can be transferred to offspring during lactation, but the effects on human infants are unknown. Animal studies did not show adverse effects on reproductive potential.

G. Pharmacokinetics:

1. Absorption: Subcutaneous bioavailability is high (~93%). Peak IgG levels (~1607 mg/dL) occur within 5 days after a weekly dose of 147 mg/kg.

2. Distribution: Steady-state levels are similar in adults and children (ages 2–16), with no major differences in AUC or bioavailability.
3. Metabolism: IgG is primarily broken down in the liver and reticuloendothelial system into peptides and amino acids. The FcRn receptor extends IgG's half-life by recycling it.
4. Excretion: Cleared at 1.6 mL/kg/day; half-life is approximately 59 days. Clearance is consistent across adult and pediatric populations.

H. Adverse Reactions:

1. Dermatologic: Erythema at injection site, Injection site pruritus
2. Gastrointestinal: Nausea (7.4%), Vomiting (7.4%)
3. Immunologic: Antibody development (18%)
4. Neurologic: Headache (21%)
5. Other: Fatigue (11.1%), Fever (7.4%)

I. Drug Interactions: drug-drug interactions may exist. Consult interaction database for patient specific assessment.

1. Local/systemic anesthetics: Increased response to anesthetic
2. Loop diuretics: Increased blood viscosity and higher risk of thromboembolic events.
3. Live vaccines: Interference with the immune response to the live vaccine
4. Ravulizumab-cwvz**:** Decreased ravulizumab-cwvz serum levels

IV. ADMINISTRATIVE GUIDELINES

A. Administration: Infusions should be given immediately after preparation. Begin infusion within 4 hours of preparation per current USP Immediate-Use Guidelines.

B. Subcutaneous Immune Globulin infusion 10% (Human) with recombinant human hyaluronidase should be administered by a healthcare professional, caregiver, or the patient themselves after appropriate training.

C. Infusion Pump Requirements

1. An infusion pump capable of delivering therapeutic doses at rates up to 300 mL/hr/site is required.
2. The pump must allow for titration of the flow rate to improve tolerability.
3. Use a subcutaneous needle set that is 24 gauge and labeled for high flow rates to ensure maximum flow rates.

D. Handling Infusion Site Leakage

1. If leakage occurs during or after subcutaneous administration, consider using longer needles (14 mm instead of a 12 mm) and/or multiple infusion sites.

V. NURSING PROCEDURE

A. Supplies may include but are not limited to:

1. Alcohol Swabs
2. Gloves

3. Tape
4. IV Pole
5. 24 G high flow needle set (12 for adults, 9 mm for pediatrics)
6. Appropriately sized syringes with needles (18 G x 1")
7. Sharps container
8. Appropriately sized empty pooling bag, if pooling vials
9. Supplies if utilizing a pole mounted ambulatory infusion pump:
    a. Ambulatory pump 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. Pump return box
10. If pooling vials:
    a. Appropriately sized empty bags for pooling
11. If administering from vials and not pooling
    a. In line or adapter vent for tubing

B. Prescription items: (examples below)

    1. Immune Globulin Infusion 10% (Human) and Recombinant Human Hyaluronidase vials

C. How Supplied: Subcutaneous Immune Globulin infusion 10% (Human) with recombinant human hyaluronidase is supplied in a dual vial unit of two single dose vials containing the labeled amount of functionally active Immune Globulin Infusion 10% (Human) and Hyaluronidase. Immune Globulin Infusion 10% (Human) should be clear or pale yellow and Hyaluronidase is clear and colorless.

D. Storage and Handling:

    1. Store vials in the carton at 2° to 8°C (36° to 46°F). Do not freeze.
    2. May be stored at temperatures up to 25°C (77°F) for up to 3 months within the first 24 months from the manufacturing date, provided it does not exceed the expiration date on the carton. Once stored at room temperature, do not return it to refrigeration.

E. Compatibility:

    1. Do not mix or administer components of subcutaneous Immune Globulin infusion 10% (Human) with recombinant human hyaluronidase with other products. Administer components of subcutaneous Immune Globulin infusion 10% (Human) with recombinant human hyaluronidase sequentially. Do not use either component alone.

F. Procedures:

    1. Explain the reasoning for visit and use of subcutaneous Immune Globulin infusion 10% (Human) with recombinant human hyaluronidase.
    2. Don gloves.
    3. Counsel patient on warnings, precautions, and potential side effects including but not limited to injection site reactions, gastrointestinal issues, fatigue, headaches, allergic reactions, hemolysis, thrombosis, aseptic meningitis, renal concerns, and potential respiratory symptoms including Transfusion-Related Acute Lung Injury (TRALI).
    4. Prepare Product:
        a. Inspect the vials for clarity, color, and expiration date(s). Do not use if cloudy or has

particulates.

b. Allow refrigerated product to reach room temperature without heating or microwaving. Do not shake.
c. Recombinant Human Hyaluronidase Preparation: Labeled as “HY”

    i. Remove the purple protective cap and the blue vial caps from the recombinant human hyaluronidase vials labeled as “HY”.
    ii. Wipe each vial stopper with a sterile alcohol wipe and allow it to dry.
    iii. Attach a sterile needle (18-22 gauge) or needle-less transfer device to a syringe. Insert the needle at a 90-degree angle into the vial stopper, inject air, and then draw the full contents of recombinant human Hyaluronidase into the syringe, if possible.
    iv. Attach the syringe containing recombinant human Hyaluronidase to the subcutaneous needle set and prime it up to the needle hub

d. Immune Globulin 10% (Human) Preparation: Labeled as “IG”

    i. Wipe each stopper with a sterile alcohol wipe and allow them to dry.
    ii. Transfer the immune globulin vial(s) using one of the following methods:

        a) Attach and prime the pump administrating tubing or directly spike the vial using a vented pump administration tubing and prime as directed.
        b) If using a syringe driver, transfer into the syringe(s), preferably using a vented spike.

e. Preparation of the infusion site

    i. Selection of Infusion Site(s)

        a) The recommended sites for subcutaneous Immune Globulin infusion 10% (Human) with recombinant human hyaluronidase infusion are the abdomen and thighs.
        b) If using two sites, they should be on opposite sides of the body.
        c) For three sites, ensure the sites are at least 10 cm apart.
        d) Avoid areas with bony prominences, scars, inflammation, or infection.
        e) Cleanse the infusion site(s) with a sterile alcohol wipe beginning at the center of each infusion site and moving outward in a circular motion. Allow the infusion site(s) to dry.

    ii. Volume per Site

        a) Primary Immunodeficiency (PI):
            - Patients ≥40 kg: Administer up to 600 mL per site.
            - Patients <40 kg: Administer up to 300 mL per site.
        b) Chronic Inflammatory Demyelinating Polyradiculoneuropathy (CIDP):
            - Patients ≥40 kg: The maximum infusion volume should not exceed 1200 mL on a given day.
            - Patients <40 kg: The maximum volume should not exceed 600 mL on a given day.
            - If the maximum volume is exceeded or not tolerated, the dose

can be administered over multiple days with a 48 to 72-hour interval between doses.
- The dose can be given at 1, 2, or 3 infusion sites, with a maximum of 600 mL per site (or as tolerated).
- If using three sites, the maximum volume is 400 mL per site.

iii. Securing the infusion site

a) Insert and secure the 24-gauge subcutaneous needle in place:
b) Pinch at least one inch of skin between two fingers. Insert the needle at a 90-degree angle into the subcutaneous tissue and secure the needle with sterile tape and check the placement.
- If using the push method: Gently pull back on the plunger of the attached syringe and monitor for any blood return in the tubing. If blood is seen in the tubing, remove and discard the needle and repeat steps 3, 5, and 6 with a new subcutaneous needle and infusion site.
- If using the pump method: Close the clamp above the lower port of the pump tubing. Clean the lower port with an alcohol swab and allow it to dry, for at least 30 seconds. Attach a 5 mL syringe to the lower port of the pump tubing. Pull back gently on the syringe plunger. If no blood, remove the syringe and open the lower port clamp.

f. Initiate Infusion - For each full or partial vial of Immune Globulin Infusion 10% (Human) used, administer the entire contents of the recombinant human hyaluronidase vial prior to the immune globulin.
   i. Recombinant Human Hyaluronidase
      a) If using push method: Infuse the recombinant human Hyaluronidase manually at an initial rate of approximately 1 to 2 mL per minute per infusion site and increase as tolerated.
      b) If using a pump method: Start at an initial rate at 60 mL to 120 mL/hr per infusion site and may increase as tolerated up to 300 mL/hr.
      c) If more than one site is used, divide the contents equally between sites. At the end of infusion, disconnect the empty syringe and attach the pump tubing/syringe containing the Immune Globulin Infusion 10% component to the same subcutaneous needle set.
   ii. Immune Globulin Infusion 10% (Human)
      a) Within approximately 10 minutes of completing the infusion of the recombinant human Hyaluronidase component, start the variable rate program of the infusion pump to initiate the infusion of the full therapeutic dose of Immune Globulin Infusion 10% (Human) component.

g. Infusion Completion
   i. After the infusion is complete, remove the needle set and cover with a protective dressing.
   ii. Discard any partially used vial(s) and disposable supplies in accordance with local requirements.

h. Documentation
    i. Record in the patient's electronic health record the time, date, dose, lot number, expiration date, infusion site location and any reactions after each infusion

5. Infusion Rates:

a. Primary Immunodeficiency (PI)

i. Recombinant Human Hyaluronidase: Infuse at an initial rate per site of approximately 1 to 2 mL per minute, or as tolerated.
ii. Immune Globulin Infusion 10% (Human): Infuse at rates as shown in Table 4 for the initial infusions. If the patient tolerates these infusions at the full dose and maximum rate, adjust both the time intervals and number of rate changes of the ramp-up used for successive infusions at the discretion of the physician and patient.

Table 4: Recommended Immune Globulin Infusion 10% (Human) Infusion Rates

	First 2 Infusions		**Subsequent 2 or 3 Infusions**	
	Subjects <40kg (<88lbs)	**Subjects ≥40kg (≥88lbs)**	**Subjects <40kg (<88lbs)**	**Subjects ≥40kg (≥88lbs)**
Intervals	Rate per site	Rate per site	Rate per site	Rate per site
Minutes	*mL per hour*	*mL per hour*	*mL per hour*	*mL per hour*
5-15	5	10	10	10
5-15	10	30	20	30
5-15	20	60	40	120
5-15	40	120	80	240
Remainder of infusion	80	240	160	300

b. Chronic Inflammatory Demyelinating Polyradiculoneuropathy (CIDP)

i. Recombinant Human Hyaluronidase: Infuse at 1 to 2 mL per minute (60 to 120 mL/hr) per site, or as tolerated.
ii. Immune Globulin Infusion 10% (Human):

a) Patients ≥40 kg:
- Initial rate of 10 mL per hour per site.
- If tolerated, gradually increase to a maximum rate of 240 mL per hour per site for the first 1-2 infusions.
- For subsequent infusions, increase the rate to a maximum of 300 mL per hour per site.

b) Patients <40 kg:
- Initial rate of 5 mL per hour per site.
- If tolerated, gradually increase to a maximum rate of 80 mL per hour per site for the first 1-2 infusions.
- For subsequent infusions, increase the rate to a maximum of 160 mL per hour per site.

6. 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. Baseline renal function and blood parameter labs
2. IgA levels

B. During therapy:

1. Therapeutic effectiveness
   a. PI: Decrease in frequency/severity of infections
   b. CIDP: Improvements in strength, mobility, and a reduction in relapse frequency
2. Renal Function/Volume status: Measure serum creatinine (sCr) prior to the first infusion and at intervals (every 1-3 months for patients with preexisting kidney impairment).
3. Blood Parameters/Blood pressure: Check IgG concentrations, hemoglobin, hematocrit, and platelets (especially in patients with ITP). Additionally, monitor blood viscosity for patients at risk for hyper viscosity (e.g., cryoglobulins, severe hypertriglyceridemia).
4. Adverse Reactions: Monitor for infusion-related reactions, anaphylaxis, thrombosis, hemolysis, and pulmonary issues, including transfusion-related acute lung injury. Additionally, observe for neurologic symptoms, particularly signs of Aseptic Meningitis Syndrome (AMS).

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

REFERENCES:

HyQvia (immune globulin 10% [Human], recombinant human hyaluronidase) injection [package insert]. Lexington, MA: Takeda Pharmaceuticals U.S.A., Inc.; 2017.

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

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.

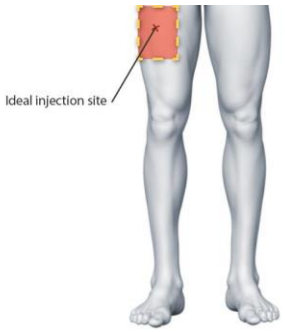
Open the supply bag labeled Epinephrine Kit Contents.

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 not to 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.