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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.

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# Infliximab (Remicade) and Biosimilars 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

Infliximab (Remicade) is a chimeric monoclonal antibody that binds to human tumor necrosis factor alpha (TNFα), thereby interfering with endogenous TNFα activity. Infliximab is indicated for several disease states such as rheumatoid arthritis, ankylosing spondylitis, psoriatic arthritis, plaque psoriasis, Crohn's disease and ulcerative colitis, which is characterized by increased TNFα in involved tissues or fluids. TNFα is known to induce pro-inflammatory cytokines (interleukins), enhance leukocyte migration, activate neutrophils and eosinophils, and induce acute phase reactants and tissue degrading enzymes.

Biosimilars: A biosimilar product is highly similar and has no clinically meaningful differences in safety, purity, and potency (safety and effectiveness) from an existing FDA-approved reference product. The manufacturer of a proposed biosimilar product generates data comparing the proposed product to the FDA-approved reference product to demonstrate biosimilarity. A manufacturer that shows its proposed biosimilar product is highly similar may rely in part on FDA's previous determination of safety and effectiveness for the reference product for approval. This generally means that biosimilar manufacturers do not need to conduct as many expensive and lengthy clinical trials, potentially leading to faster access to these products, additional therapeutic options, and reduced costs for patients. Biosimilar products may have different inactive or excipient ingredients than the reference product.

Multiple biosimilars for Infliximab (Remicade®) are available in the United States including Inflectra® (infliximab-dyyb), Renflexis® (infliximab-adba), and Avsola® (infliximab- axxq). When dispensing biosimilar products, the four-letter suffix (ex: infliximab- dyyb) must be present after the generic drug name to distinguish which biosimilar product is dispensed.

The following outlines the procedures for servicing patients in need of outpatient infliximab 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 infliximab must include:

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

D. Baseline labs or tests prior to starting therapy

1. Tuberculosis screening with PPD (purified protein derivative) skin test or Quantiferon Gold test
2. Hepatitis B laboratory testing

E. Dispensing pharmacy treatment protocol for anaphylaxis will be instituted unless more comprehensive patient-specific orders are provided by physician.
(See Appendix A - Nursing 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. Treatment of adults and children ≥ 6 years with moderately- to severely active Crohn's disease with inadequate response to conventional therapy
2. Treatment of adults and children ≥ 6 years with moderately- to severely active ulcerative colitis with inadequate response to conventional therapy
3. Treatment of adults with moderately- to severely- active rheumatoid arthritis
4. Treatment of adults with active ankylosing spondylitis
5. Treatment of adults with psoriatic arthritis
6. Treatment of adults with chronic severe plaque psoriasis as an alternative to other systemic therapy

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

B. Dosing:

1. **Crohn's disease (both adult and pediatric)**: 5 mg/kg at 0, 2 and 6 weeks, then every 8 weeks. Some adult patients who initially respond to treatment may benefit from increasing the dose to 10 mg/kg every 8 weeks if they later lose their response.

2. **Ulcerative colitis (both adult and pediatric)**: 5 mg/kg at 0, 2 and 6 weeks, then every 8 weeks

3. **Rheumatoid arthritis (adult patients)**: In conjunction with methotrexate, 3 mg/kg at 0, 2 and 6 weeks, then every 8 weeks. Some patients may benefit from increasing the dose up to 10 mg/kg every 8 weeks or treating as often as every 4 weeks.

4. **Ankylosing spondylitis (adults)**: 5 mg/kg at 0, 2 and 6 weeks, then every 6 weeks

5. **Psoriatic arthritis and plaque psoriasis (adults)**: 5 mg/kg at 0, 2 and 6 weeks, then every 8 weeks.

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

C. Dose Adjustment

1. NYHA Class I/II Heart Failure- No dosage adjustment necessary; use in caution and monitor closely for worsening of heart failure
2. NYHA Class III or IV Heart Failure- utilize a dose ≤ 5 mg/kg
3. No hepatic or renal impairment dose adjustments

D. Duration: Duration of therapy should be dependent on patient response and adverse reaction. Adult patients with Crohn's Disease receiving infliximab who do not respond by Week 14 are unlikely to respond with continued dosing. Consideration should be given to discontinue therapy for these patients.

E. Contraindications: Hypersensitivity to infliximab, murine proteins or any component of the formulation. Doses>5 mg/kg in patients with moderate or severe heart failure (NYHA Class III/IV)

F. Warnings and Precautions:

1. **Infections:** Patients receiving infliximab are at increased risk for serious infection which may result in hospitalization and/or fatality. Active tuberculosis, invasive fungal and bacterial, viral or other opportunistic infections have been reported. Monitor closely for signs/symptoms of infection. Discontinue for serious infection or sepsis. Consider risks versus benefits prior to use in patients with a history of chronic or recurrent infection. Consider empiric antifungal therapy in patients who are at risk for invasive fungal infection and develop severe systemic illness.

2. **Hepatitis B Virus:** Reactivation of hepatitis B virus has occurred in chronic carriers of the virus. In some instances, HBV reactivation occurring in conjunction with TNF blocker therapy has been fatal. Most of these reports have occurred in patients concomitantly receiving other medications that suppress the immune system, which may also contribute to HBV reactivation. Patients should be tested for HBV infection before initiating infliximab.

3. **Tuberculosis**: Infliximab treatment has been associated with active tuberculosis (may be disseminated or extra pulmonary) or reactivation of latent infections. Evaluate patients for tuberculosis risk factors and latent tuberculosis infection prior to and during therapy. Treatment of latent tuberculosis should be initiated before starting infliximab. Patients with initial negative tuberculin skin tests should receive continued monitoring for tuberculosis throughout treatment.

4. **Malignancy:** Lymphoma and other malignancies have been reported in children and adolescent patients receiving TNF-blocking agents including infliximab. Post-marketing cases of

hepatosplenic T-cell lymphoma have been reported in patients treated with infliximab. Almost all patients had received concurrent or prior treatment with azathioprine or mercaptopurine at or prior to diagnosis and the majority of reported cases occurred in adolescent and young adult males with Crohn disease or ulcerative colitis. The potential role of TNF blockers in the development of malignancies is not known. Rates in clinical trials for infliximab cannot be compared to rates in clinical trials of other TNF blockers and may not predict rates observed in a broader patient population. Caution should be exercised in considering infliximab treatment in patients with a history of malignancy or in continuing treatment in patients who develop malignancy while receiving infliximab.

5. **Hepatotoxicity:** Severe hepatic reactions including acute liver failure, jaundice, hepatitis, and cholestasis have been reported during treatment. Severe hepatic reactions occurred between 2 weeks to > 1 year after initiation of therapy and some cases were fatal or necessitated liver transplantation. Patients with symptoms or signs of liver dysfunction should be evaluated for evidence of liver injury. Discontinue with jaundice and/or increased liver enzymes (> 5 times ULN). In clinical trials, mild or moderate elevations of ALT and AST have been observed in patients receiving infliximab without progression to severe hepatic injury.

6. **Heart Failure**: The use of infliximab at doses >5 mg/kg is contraindicated in patients with moderate or severe heart failure. A randomized, double-blind, placebo-controlled study evaluated the use of infliximab (5 mg/kg or 10 mg/kg at Weeks 0, 2, and 6) in patients with moderate or severe heart failure [New York Heart Association (NYHA) Functional Class III/IV]. Compared to patients who received placebo, there was a higher rate of mortality and a higher risk of hospitalization at Week 28 due to heart failure in patients who received the 10 mg/kg dose, and higher rates of cardiovascular adverse events in patients who received infliximab doses of 5 mg/kg and 10 mg/kg. There have been post-marketing reports of new onset and worsening heart failure, with and without identifiable precipitating factors (e.g., pre-existing cardiovascular disease), in infliximab-treated patients. Some of these patients have been under 50 years of age. If a decision is made to administer infliximab (≤ 5 mg/kg) to patients with moderate or severe heart failure or to administer infliximab (any approved dose) to patients with mild heart failure, they should be closely monitored during therapy, and therapy should be discontinued if new or worsening symptoms of heart failure appear

7. **Hematologic disorders:** Cases of leukopenia, neutropenia, thrombocytopenia, and pancytopenia, some with a fatal outcome, have been reported in patients receiving infliximab. The causal relationship to infliximab therapy remains unclear. Although no high-risk group(s) has been identified, caution should be exercised in patients being treated with infliximab who have ongoing or a history of significant hematologic abnormalities. All patients should be advised to seek immediate medical attention if they develop signs and symptoms suggestive of blood dyscrasias or infection while receiving infliximab. Discontinuation of therapy should be considered in patients who develop significant hematologic abnormalities. Use in caution with patients with history of hematologic abnormalities.

8. **Hypersensitivity reactions:** Infliximab has been associated with hypersensitivity reactions that vary in their time of onset and required hospitalization in some cases. Most hypersensitivity reactions (including anaphylaxis, urticaria, dyspnea, and/or hypotension), have occurred during or within 2 hours of the infusion.

   In some cases, serum sickness-like reactions have been observed in patients after initial infliximab therapy (i.e., as early as after the second dose), and when therapy was reinstituted

following an extended period without treatment. Symptoms associated with these reactions include fever, rash, headache, sore throat, myalgias, polyarthralgias, hand and facial edema and/or dysphagia. These reactions were associated with a marked increase in antibodies to infliximab, loss of detectable serum concentrations of infliximab, and possible loss of drug efficacy.

Medication and equipment for management of hypersensitivity reaction should be available for immediate use. Consider pretreatment, may be warranted in all patients with prior infusion reactions.

9. **Cardiovascular and Cerebrovascular Reactions:** Transient visual loss has been reported during or within two hours of infusion. Myocardial ischemia/infarction, hypotension, hypertension, and arrythmias may occur within 24 hours of infusion. Review medical history prior to initiation and monitor before and immediately after infusion.

10. **Neurologic Reactions:** Infliximab and other agents that inhibit TNF have been associated with central nervous system manifestation of systemic vasculitis, seizure and new onset or exacerbation of clinical symptoms and/or radiographic evidence of central nervous system demyelinating disorders, including multiple sclerosis and optic neuritis, and peripheral demyelinating disorders, including Guillain-Barré syndrome. Prescribers should exercise caution in considering the use of infliximab in patients with these neurologic disorders and should consider discontinuation of infliximab if these disorders develop.

11. **Concurrent administration with other biologics**: Serious infections and neutropenia were seen in clinical studies with concurrent use of anakinra and another TNF blocker, etanercept, with no added clinical benefit compared to etanercept alone. Because of the nature of the adverse reactions seen with the concurrent use of etanercept and anakinra therapy, similar toxicities may also result from the concurrent use of anakinra and other TNF blockers such as infliximab. There is insufficient information regarding the concurrent use of infliximab with other biological products used to treat the same conditions. The concurrent use of infliximab with these biological products is not recommended because of the possibility of an increased risk of infection.

12. **Autoimmune Disorders**: Positive antinuclear antibody titers have been detected in patients, with negative baseline; rare cases of autoimmune disorder, including lupus-like syndrome, have been reported. Monitor and discontinue if symptoms develop.

13. **Vaccinations:** Prior to initiating infliximab, ensure patient is up to date on vaccinations. The concurrent administration of live vaccines with infliximab is not recommended.

14. **Pregnancy:** Available observational studies in pregnant women exposed to infliximab showed no increased risk of major malformations among live births as compared to those exposed to non-biologics. However, findings on other birth and maternal outcomes were not consistent across studies of different study design and conduct. Monoclonal antibodies such as infliximab are transferred across the placenta during the third trimester of pregnancy and may affect immune response in the in utero exposed infant. Because infliximab does not cross-react with TNFα in species other than humans and chimpanzees, animal reproduction studies have not been conducted with infliximab. In a developmental study conducted in mice using an analogous antibody, no evidence of maternal toxicity or fetal harm was observed. All pregnancies have a background risk of birth defect, loss, or other adverse outcomes.

15. **Lactation**: Published literature show that infliximab is present at low levels in human milk. Systemic exposure in a breastfed infant is expected to be low because infliximab is largely degraded in the gastrointestinal tract. A U.S. multi-center study of 168 women treated with infliximab for inflammatory bowel disease (breast milk samples obtained, n=29) showed that infants exposed to infliximab through breast milk had no increase in rates of infections and developed normally. There are no data on the effects of infliximab on milk production. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for infliximb and any potential adverse effects on the breastfed child from infliximab or from the underlying maternal condition

G. Pharmacokinetics:

1. Onset of action: 1-2 weeks in Crohn's Disease, 3-7 days in patients with rheumatoid arthritis
2. Volume of distribution at steady state was independent of dose and indicated that infliximab was distributed primarily within the vascular compartment.
3. Drug concentration levels: No systemic accumulation of infliximab occurred upon continued repeated treatment with 3 mg/kg or 10 mg/kg at 4- or 8-week intervals. At 8 weeks after a maintenance dose of 3 to 10 mg/kg of infliximab, median serum concentrations ranged from approximately 0.5 to 6 mcg/mL. Development of antibodies to infliximab increased clearance. Infliximab concentrations were undetectable in patients who became positive for antibodies to infliximab.
4. Half-life elimination: ~14.7 days in healthy adults, ~12.4 days in adult patients with Crohn's disease, and ~13.2 days in pediatric patients with Crohn's disease

H. Adverse Reactions:

1. Cardiovascular: Hypertension (3-7%)
2. Gastrointestinal: Nausea 21%; Diarrhea 5%; Abdominal pain 3-12%
3. Hematologic: Anemia 5-11%
4. Hepatic: Increased serum ALT (up to 51%) - risk increased with concomitant use of methotrexate. Increased liver enzymes 18%; (1) ≥5 times ULN 1%
5. Increased ANA titer (~50%)
6. Infection 30-60%
7. Infusion related reactions 13-20%; severe infusion related reactions < 1%
8. Musculoskeletal: Arthralgia (4-8%)
9. Neurologic: Headache 18%
10. Respiratory: Upper respiratory tract infection 7-32%; Sinusitis 14%; Cough 12%; Pharyngitis 8-12%

I. Drug Interactions:

1. **Other Biologic Products**: The combination of infliximab with other biological products used to treat the same conditions as infliximab is not recommended. An increased risk of serious infections was seen in clinical studies of other TNF blockers used in combination with anakinra or abatacept, with no added clinical benefit. Because of the nature of the adverse reactions seen with these combinations with TNF blocker therapy, similar toxicities may also result from the combination of anakinra or abatacept with other TNF blockers such as infliximab.

2. **Methotrexate and Other Concomitant Medications**: Concomitant methotrexate use may

decrease the incidence of anti-infliximab antibody production and increase infliximab concentrations. Concurrent use of methotrexate and hepatotoxic agents may result in increased methotrexate exposure, an increased risk of methotrexate-related severe adverse reactions, reduced active metabolite formation and possibly reduced methotrexate efficacy.

3. **Immunosuppressants:** Patients with Crohn's Disease who received immunosuppressants tended to experience fewer infusion reactions compared to patients on no immunosuppressants. Serum infliximab concentrations appeared to be unaffected by baseline use of medications for the treatment of Crohn's including corticosteroids, antibiotics (metronidazole or ciprofloxacin) and aminosalicylates.

4. **Cytochrome P450 substrates**: The formation of CYP450 enzymes may be suppressed by increased levels of cytokines (e.g., TNFα, IL-1, IL-6, IL-10, IFN) during chronic inflammation. Therefore, it is expected that for a molecule that antagonizes cytokine activity, such as infliximab, the formation of CYP450 enzymes could be normalized. Upon initiation or discontinuation of infliximab in patients being treated with CYP450 substrates with a narrow therapeutic index, monitoring of the effect (e.g., warfarin) or drug concentration (e.g., cyclosporine or theophylline) is recommended and the individual dose of the drug product may be adjusted as needed.

5. **Live Vaccines/Therapeutic Infectious Agents:** Live vaccines or use of a therapeutic infectious agents (e.g. Bacillus Calmette-Guerin [BCG]) should not be given concurrently during infliximab treatment. Immunosuppressants may diminish the therapeutic effect of vaccines and may enhance the adverse effects of vaccines. Live attenuated vaccines should not be given for at least 3 months after last infliximab dose. It is also recommended that live vaccines not be given to infants after in utero exposure to infliximab for at least 6 months following birth. Ensure patients are up-to-date with vaccinations prior to starting infliximab.

* Consult interaction database for patient specific assessment.

## IV. ADMINISTRATIVE GUIDELINES

A. Administration: Intravenous infusion should begin within 3 hours of reconstitution and dilution.

B. Use an in-line or add-on **0.2-micron low protein binding filter.** (filter must be a pore size of 1.2 μm or less).

C. Do not co-administer with other products in the same line.

## 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
    - IV start Kit
    - Peripheral IV catheter (ex. 22 Gauge x1" and 24 Gauge x ¾")
    - Extension set 8" with needless connector
b. Port access supplies for patients with a port
    - Port needle (ex. 22 Gauge x ¾ to 1" safe step)
    - Extension set 8" needless connector
    - Central line dressing change kit

5. IV Pole
6. IV administration set (flow regulator or gravity) with in-line or add-on **0.22 micron filter**

7. Supplies if utilizing a pole mounted ambulatory infusion pump:
    a. Ambulatory pump tubing with **0.22 micron filter**
    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
8. Syringes (10-30mL) with needles (20 G x 1")
9. Sharps container

B. Prescription items:

1. Infliximab vials
2. 0.9% Normal saline bag stock bag or prefilled bag
3. Sterile water for injection vials
4. Standard flushes per protocol

C. How Supplied:

Infliximab and biosimilars are provided as lyophilized 100mg drug per vial for reconstitution with 10 mL SWFI. Refer to specific product packing and prescribing information for NDC, storage, stability, and excursion information.

D. Storage and Handling:

1. Store vials in the refrigerator at 2ºC to 8ºC (36ºF to 46ºF).
2. If needed, unopened infliximab vials may be stored at room temperatures up to a maximum of 30ºC (86°F) for a single period of up to 6 months but not exceeding the original expiration date. The new expiration date must be written in the space provided on the carton. Once removed from the refrigerator, infliximab cannot be returned to the refrigerator.

E. Compatibility: Stable in 0.9% normal saline solution

F. Procedures:

1. Explain the reasoning for visit and use of infliximab.
2. Don gloves.
3. Assess for signs and symptoms of infection prior to establishing venous access and preparing medication.

4. Establish venous access prior to preparation of drug.
5. Counsel patient on warnings, precautions, and potential side effects including but not limited to infections, headache, nausea, diarrhea, abdominal pain, and infusion related reactions
6. Administer any pre-medications 30 minutes prior to the infusion
7. Prepare Product:

    a. Reconstitute vials with 10 ml sterile water for injection. Swirl vial gently to dissolve powder. Do not shake. Allow solution to stand for 5 minutes.
    b. Visually inspect the reconstituted solution for particulate matter and discoloration. The reconstituted solution should be colorless to light yellow and opalescent, and the solution may develop a few translucent particles as infliximab is a protein.
    c. If using a stock saline bag, prior to adding drug, withdraw same volume of saline from bag as the amount of drug that will be added for total volume. Discard excess saline. Prefilled saline bags will not require this step.
    d. Draw up total dose and slowly inject into bag of 0.9% Sodium Chloride. The resulting infusion concentration should range between 0.4-4mg/mL
    e. The infusion should begin within 3 hours of reconstitution and dilution

8. Infusion Rates:

    a. Infusions will be administered continuously over two hours or per ordered titration unless previous infusion history dictates a slower rate.
    b. Patients with established tolerance may be candidates for infusion times less than two hours. Appropriateness will be reviewed with the prescriber on a case-by-case basis.

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

## VI. CLINICAL MONITORING

A. Prior to therapy

1. Assess baseline laboratory work including CMP and CBC
2. TB screening
3. Hepatitis B virus screening
4. Ensure patients are up to date on vaccinations
5. Signs/symptoms of infection
6. Assess patients with heart failure and appropriateness of dose

B. During therapy

1. Monitor improvement of symptoms and physical function assessments
2. Assess for signs/symptoms of infection throughout therapy.
3. Monitor for signs/symptoms of infusion related reactions or hypersensitivity reactions. Slow infusion rate down if needed.
4. Monitor for symptoms of lupus-like syndrome including muscle weakness, flu-like symptoms, fevers, chills, and inflammation/ discomfort around the lungs or heart.

5. Monitor for any new malignancies (ex: splenomegaly, hepatomegaly, abdominal pain, persistent fever, night sweats, weight loss). Psoriasis patients with history of phototherapy should be monitored for nonmelanoma skin cancer
6. Monitor CMP and LFTs. Discontinue if LFTs are greater than 5 times the upper limit of normal.
7. Monitor CBC/platelets for any hematological reactions and cytopenia
8. Assess patients for any neurological reactions including new seizures, optic neuritis, or systemic vasculitis.
9. Avoid concurrent use with other biologics or Disease-Modifying Antirheumatic Drugs (DMARDs)

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

**REFERENCES:**


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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**

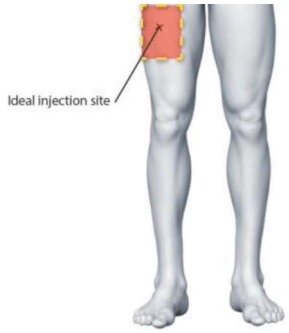
1. **Remove 1 of each item**
    a. 1 -syringe
    b. 1 – brown labeled filter needle (BD Filter Needle)- **for ampule use only**
    c. 1 – black labeled safety needle (Magellan Hypodermic Safety Needle 22G x 1”)
    d. 1 ampule of epinephrine

**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.