Nurse Link

BY CAREPATHRX

Home Biologic Therapies

2023

CAREPATHrx™

Specialty Pharmacy & Infusion Solutions

Learning Goals

By the end of this module, nurse learners will be able to:

- Apply knowledge of home infusion biologic therapy to daily nursing practice.
- Identify appropriate NurseLink resources (nurse education, patient education, annual updates, infusion and enteral videos, infusion and enteral teaching guides, pump administration brochure, FAQs, administration of emergency medications video, policies and procedures),for home infusion patients to promote effective learning to safely administer home infusion therapy.
- Apply NurseLink policies and procedures to daily nursing practice for home infusion patients.
- Apply best practice in all modes of administration when teaching and caring for home infusion patients.
- Identify signs and symptoms of reaction (mild, moderate or severe) and how to manage a reaction.
- Analyze and synthesize home infusion therapy orders, plan of treatments, product labels, and resources for application in the clinical setting.
- Identify opportunities to prevent medication errors and patient adverse events.
- Knowledge of compounding of medications.

Access to Nurse Link

To login, follow the link below and click "*Login to Nurse Link*."

https://carepathrxllc.com/nurselink-welcome/

Password: email nursingsupport@homeinfusion.com

Be sure to bookmark this URL and save your password for future use.

NL Patient Site:
https://carepathrxllc.com/nurselink-patient/

Patient teaching Videos	Patient Written Instructions	Nursing P & P	Links to RN virtual training	Nurse Videos	Home Infusion Society links	CarepathRX in the News

CAREPATHrx™
Specialty Pharmacy & Infusion Solutions

CarepathRx On Call

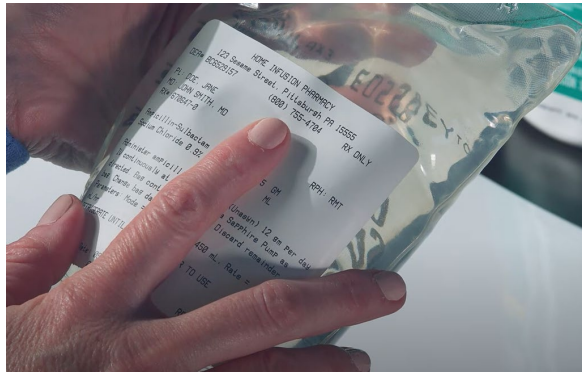
24 / 7 Access to the Clinical Pharmacy team

For after-hours, weekend and holiday support, troubleshooting, and delivery needs:

- CarepathRx Pharmacist
- Local pharmacy support varies by pharmacy.
- Dietitians

  1-877-ENTERAL
- Nurses
- Delivery

Contact the pharmacy by calling the phone number at the top of the medication label.



CAREPATHrx™
Specialty Pharmacy & Infusion Solutions

Therapy Education

- Remind patients pumps must be returned to your pharmacy when therapy is completed.
  - Pumps are not disposable
- Supply reordering
  - Patients must speak to a pharmacy assistant to reorder supplies and schedule delivery
- Will need for re-deliveries:
  - List of supplies, medications and formula needed.
  - Complete inventory of supplies, medications and formula in the home.
  - Script for order changes & when next doctor appointment is.

Pharmacy Remote Patient Monitoring

Before each delivery the pharmacist, or pharmacy representative, will assess patient standard assessment questions.

1. Is the infusion being infused safely and with appropriate technique?
2. Is the patient experiencing side effects?
3. Is the patient experiencing wear-off effects?
4. Obtain an accurate inventory of medication and supplies in the home (and what is needed).

Side effects and wear-off symptoms will be reported to the physician with order change suggestion.

These types of communication may in some cases delay your delivery.

CAREPATHRx
Pump Returns

CarepathRx will contact the patient & arrange pump pick up by UPS.

- The pharmacy will print and deliver a UPS shipping label and a padded shipping box to the patient for pump return at end of therapy.
- The patient does not need to be home for the UPS driver to pick up the boxed pump.
- There is no fee to the patient for this service.

Nurses are NOT to remove pumps from patients' homes.

(exceptions may apply)

Contact CarepathRx for equipment return.

CAREPATHrx™
Specialty Pharmacy & Infusion Solutions

WHAT ARE MONOCLONAL ANTIBODIES?

- Monoclonal antibodies (also called moAbs or mAbs) are proteins made in laboratories that act like proteins called antibodies in our bodies.

- Antibodies are parts of your immune system. They seek out the antigens (a toxin or other foreign substance which induces an immune response) and stick to them in order to destroy them.

- Laboratory-made monoclonal antibodies help stimulate your own immune system.

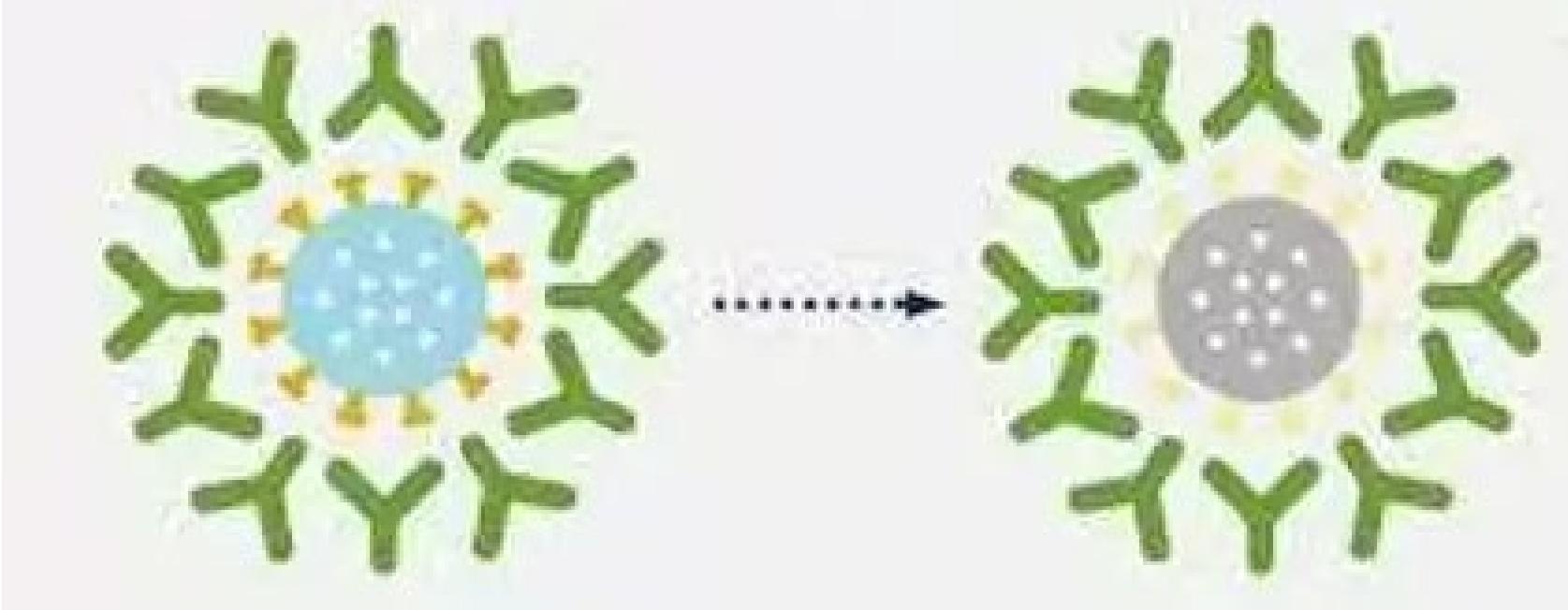
- The word “monoclonal” refers to the fact that the antibodies created in the laboratory are clones. They are exact copies of one antibody. The generic names of the products often include the letters “mab” at the end of the name.

WHAT TYPES OF DISEASES DO MONOCLONAL ANTIBODIES TREAT?

Monoclonal antibodies have been used to treat the following conditions:

- Cancer.
- Organ transplant rejection.
- Inflammatory and autoimmune disorders, including allergies.
- Infections, including COVID-19.
- Osteoporosis.
- Eye conditions.
- Migraines.
- High cholesterol.
- Nervous system disorders.

HOW MONOCLONAL ANTIBODIES ARE USED



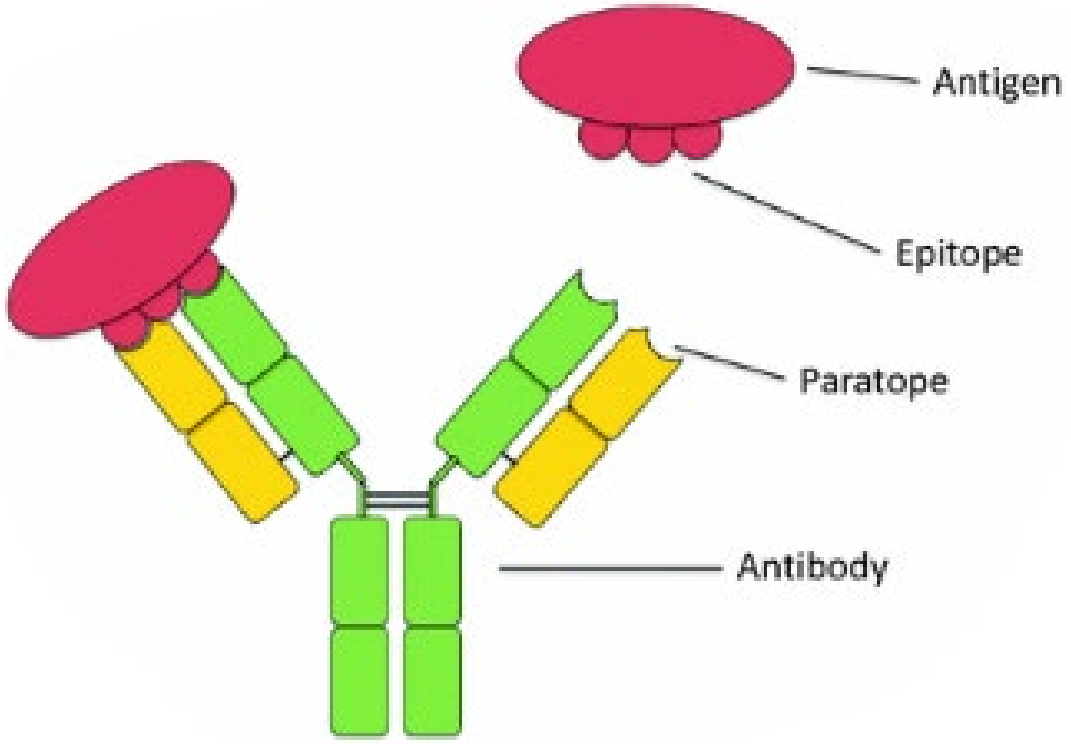
Monoclonal antibiodies
Bind to their target

once attached,
they make it harmless

Epitopes, also known as antigenic determinants, are the immunologically active discrete sites on the antigen molecule that physically bind to antibodies, B-cell receptors, or T-cell receptors.

An epitope is the part of an antigen that the host's immune system recognizes, eliciting the immune response to an invading pathogen.

Once epitope and receptor bind together in this puzzle-like combination, the production of antibodies is stimulated.



WHAT ARE THE RISKS OR COMPLICATIONS OF USING MONOCLONAL ANTIBODIES?

Infusion reactions are common and occur during or shortly after monoclonal antibody treatment. These occur when your body has a strong immune response to the monoclonal antibody treatment. Common signs of infusion reaction are rash, fever, rigors/chills, shortness of breath, sweating, changes in blood pressure and increased heart rate. Slowing down the infusion or decreasing the dose can help limit such reactions.

Monoclonal Antibody Concerns

Immune system & infusion reactions

- Increased risk for developing infections.
- Patients should be up-to-date on vaccines before stating therapy (may receive non-live vaccines, but risks increased with live vaccines)
  - Use caution to prevent infection
    - Including PML (Progressive Multifocal Leukoencephalopathy –CNS infection)

Liver injury

Lymphoma and other malignancies

Anaphylactic reaction

mAb-specific concerns: (ex - Remicade: heart failure, demyelinating disease, lupus-like syndrome, cardiovascular & cerebrovascular reactions.)

Drug interactions: co-administration with other mAbs. Refer to prescriber for dosing interval.

WHAT ARE THE RISKS OR COMPLICATIONS OF USING MONOCLONAL ANTIBODIES

Needle site reactions include:
- pain
- swelling
- soreness
- redness
- itchiness
- rash

Flu-like symptoms include:
- chills
- fatigue
- fever
- muscle aches and pains
- nausea
- vomiting
- diarrhea

- mouth and skin sores that can lead to serious infections
- high blood pressure
- congestive heart failure
- heart attacks
- inflammatory lung disease

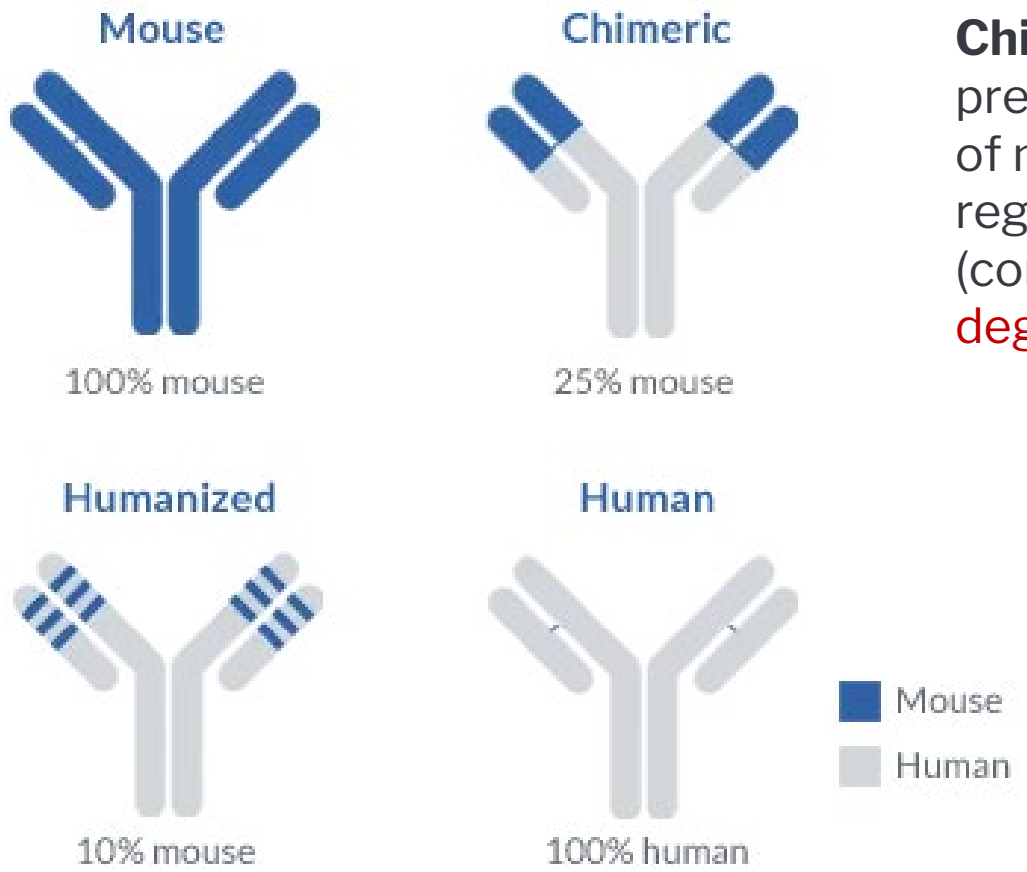
Some people do have serious reactions to monoclonal antibody therapy. More serious side effects that may cause your healthcare provider to stop monoclonal antibody therapy include:

- Very low blood counts
- Heart problems including irregular heartbeat, heart failure, and an increased risk of heart attack
- Low levels of magnesium, potassium, or calcium in your blood, which can cause serious health problems
- Serious skin rashes that lead to infections
- Bleeding problems
- Immediate reactions to the infusion including shortness of breath, wheezing, hoarseness, fainting, dizziness, blurred vision, nausea, or chest pain or pressure

Types of Monoclonal Antibodies

Mouse mAb (-omab)**:** It contains 100% mouse-derived proteins. Highest risk of anaphylactic reaction in humans.

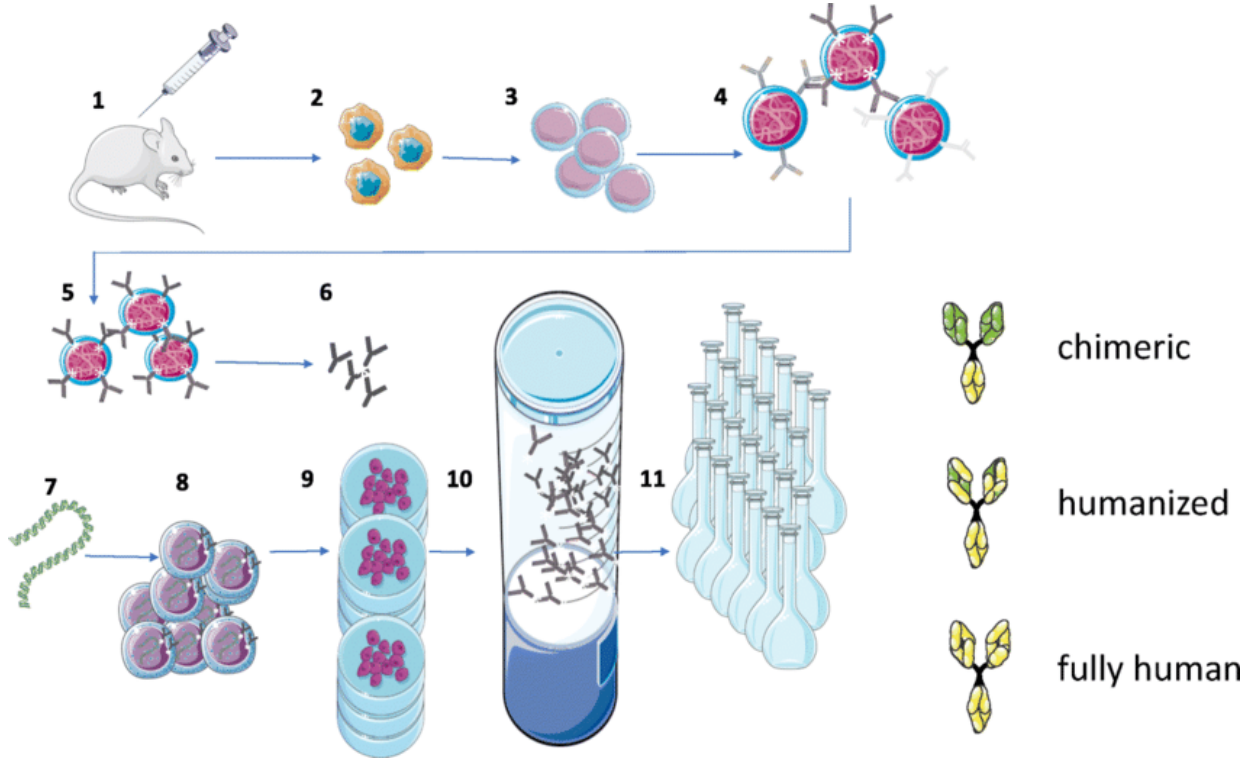
Humanized mAb (-zumab): Here, only the antigen-binding site (i.e. CDR-complementarity determining region) is mouse-derived (10%) and the remaining part of mAb is human-derived



Chimeric mAb (-ximab)**:** It is prepared by recombination of mouse proteins (variable region) and human proteins (constant region). Variable degrees of anaphylactic risk.

Human mAb (-umab): It contains 100% human-derived amino acids. It is the best-accepted mAb in humans. Lowest risk for anaphylactic reaction.

CAREPATHrx™
Specialty Pharmacy & Infusion Solutions



Manufacture of monoclonal antibodies. 1. Immunize mouse (or other animal) with antigen of interest. 2. Isolate murine plasma cells (Specialized forms of antibody-producing B-LYMPHOCYTES. They synthesize and secrete immunoglobulin. They are found at sites of immune responses and normally do not circulate in the blood or lymph) expressing antibody targeting antigen. 3. Fuse with myeloma immortalized line of cells. 4. Generate hybridomas (produce clonally identical antibodies) secreting the mAb. 5. Isolate clone producing the optimal antibody. 6. Assay antibody to ensure reactivity. 7. Clone antibody gene. 8. Express in Chinese hamster ovary cells. 9. Cell culture. 10. Bioreactor. 11. Harvest, filtration, purification, and quality control.

Types of Monoclonal Antibodies

Common Antibody Origin	INN Substem	Representative Examples
Chimeric	**-xi-**	Abci**xi**mab, Ritu**xi**mab, Infli**xi**mab, Cetu**xi**mab
Humanized	**-zu-**	Paliviz**u**mab, Trastuz**u**mab, Bevaciz**u**mab, Natali**zu**mab
Human	**-u-**	Adalim**u**mab, Panit**u**mumab Golim**u**mab, Ipilim**u**mab

Chimeric mAb (-ximab)**:** It is prepared by recombination of mouse proteins (variable region) and human proteins (constant region). Variable degrees of anaphylactic risk.

Humanized mAb (-zumab): is mouse-derived (10%) and the remaining part of mAb is human-derived

Human mAb (-umab): It contains 100% human-derived amino acids. It is the best-accepted mAb in humans. Lowest risk for anaphylactic reaction.

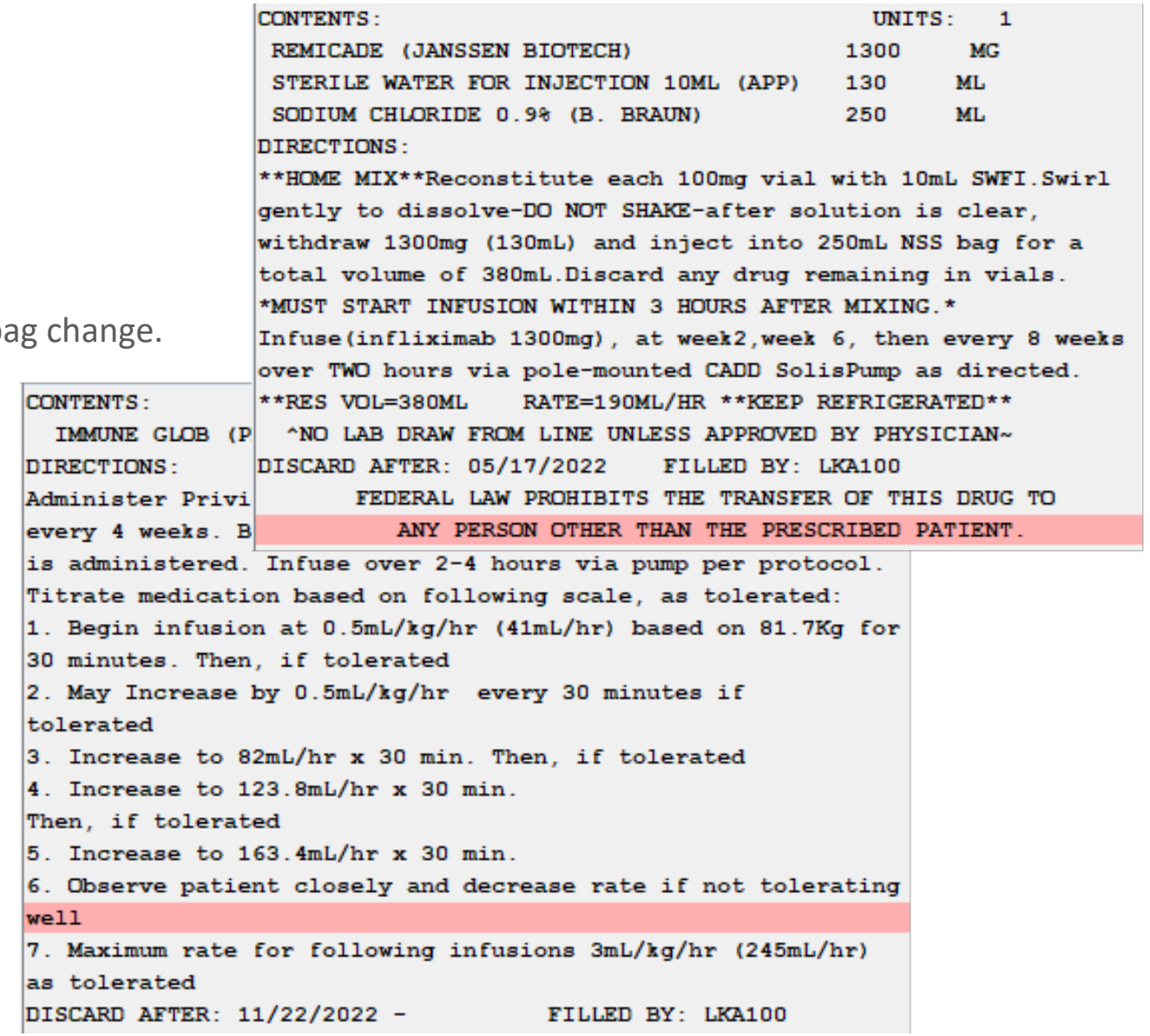
Product Label

Product label to be reviewed with each dose or bag change.

Pump settings to be reviewed on the pump with each dose or bag change.

Product label components to review:

- Patient name
- Medication name
  - Amount in bag/cassette
  - Diluent name and volume
  - Can calculate concentration
- Administration instructions
  - Plan language instructions
  - Pump parameters
    - To be verified on pump with each bag change.
  - How often to change the bag if continuous
- Storage instructions
  - Including how long to warm to room temperature if refrigerated.
- Expiration date



CAREPATHrx™
Specialty Pharmacy & Infusion Solutions

In Home Administration Considerations

Product with short half life. Must have IV access secured before compounding product in the home.

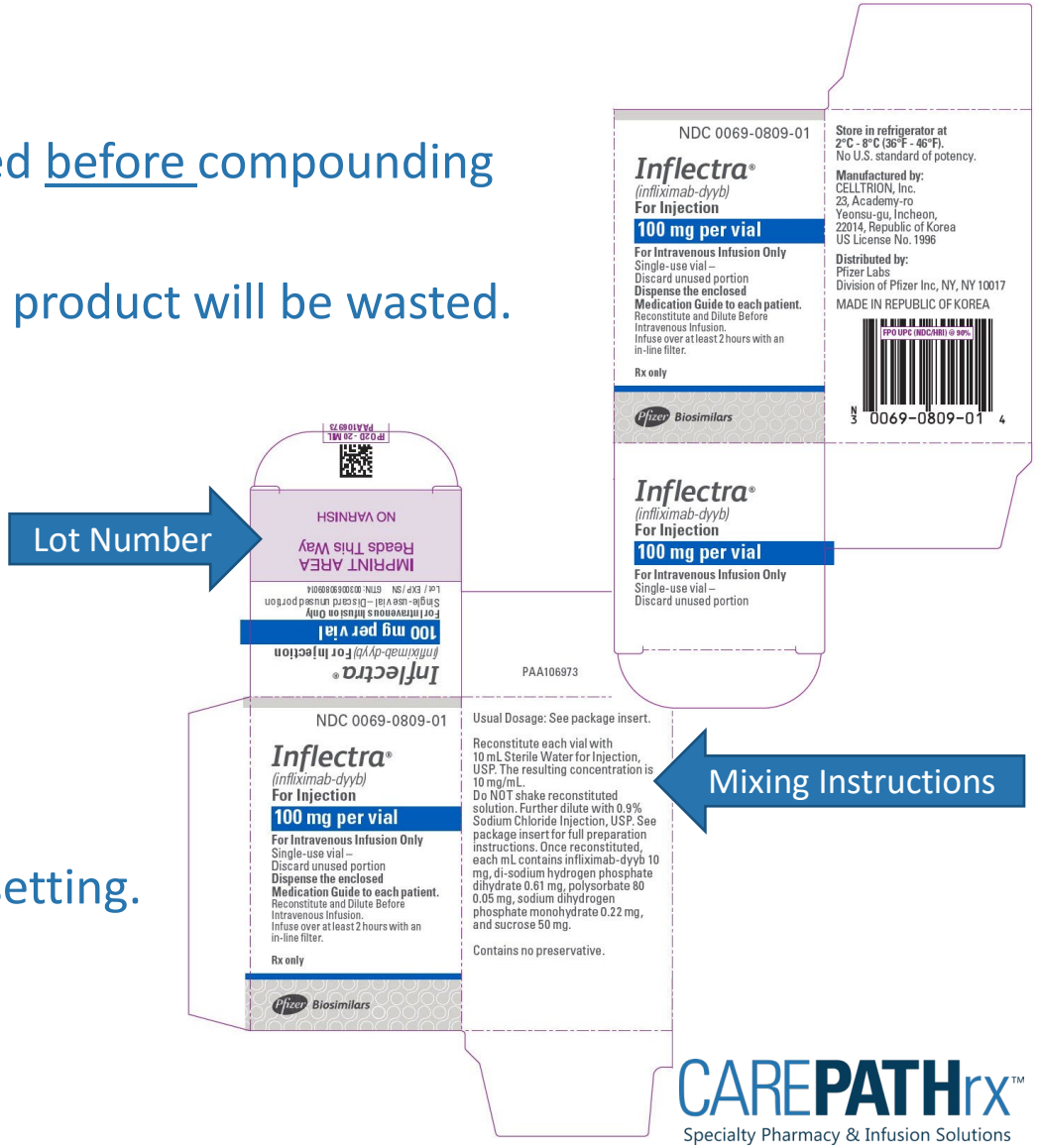
- If not able to infuse mixed drug within a few hours, product will be wasted.
- Patients will be billed for wasted vials.

Emergency plan in place

- Access to EMS.
- Emergency medications in the home.

Does the patient have prior mAb reaction history?

- May need to pre-medicate patient prior to infusion
- May need to transition site of care to a controlled setting.



CAREPATHrx™
Specialty Pharmacy & Infusion Solutions

Common Biologic Therapies in the Home

Remicade (Infliximab) - rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis, plaque psoriasis, ulcerative colitis (6y/o and older), & crohn's disease (6y/o and older)

Biosimilars: Inflectra, Avsola, Renflexis

Entyvio (vedolizumab) - crohn's disease & ulcerative colitis

Rituxan (Rituximab) - arthritis

Trogarzo (Ibalizumab) - HIV

Stelara (ustekinumab) – crohn's disease & ulcerative colitis

Tepezza (teprotumumab) – thyroid eye disease (TED)

Skyrizi (risankizumab) – plaque psoriasis, psoriatic arthritis, & crohn's disease (IV to SC injection)

Ocrevus (ocrelizumab) - MS

Benlysta (belilmumab) – lupus, lupus nephritis

Saphnelo (anifrolumab) - lupus

Common Home Infusion Therapy Biologics

Infliximab

(Remicade, Inflectra, Avsola, Renflexis)

Chimeric

Inhibits αTNF (tumor necrosis factor (TNF) functional activity.

Rheumatoid arthritis Psoriatic arthritis Ankylosing spondylitis Plaque psoriasis Ulcerative colitis (6y/o and older)
Crohn's disease (6y/o and older)

Contraindicated with hypersensitive reactions and dose adjustment for CHF.

Package insert label (fda.gov)

Vedolizumab

(Entyvio)

Humanized

Reduces GI inflammation by binding with α4β7 integrin to inhibit migration memory T-lymphocytes to inflamed GI parenchymal tissue.

Crohn's Disease
Ulcerative colitis

Web resources: Dosing and Administration | ENTYVIO (vedolizumab) (entyviohcp.com)

Package insert: ENTYVIOPI (takedapharm.com)

CAREPATHrx™
Specialty Pharmacy & Infusion Solutions

Infliximab (Remicade)

Adult dosing typically: 5mg/kg IV weeks 0, 2, 6, then Q8wks

See package insert for disease specific dosing.

Supplies

- IV supplies to insert or access vascular access device.
- Medication bag (0.9% Sodium Chloride)
- Infliximab vial(s)
- Sterile water vial(s)
- 10mL syringe(s) with needle
- Antiseptic cleanser
- CADD Solis pump
- CADD Solis tubing with 1.2-micron filter
- 4-AA batteries for emergency backup
- 0.9% NaCl prefilled syringe
- Heparin prefilled syringe (if indicated)

Prior to mixing

- Check vitals and request patient health history (illnesses).
- Insert/access intravenous catheter and ensure patency.
- Gather supplies.
- Ensure emergency medication is readily available (if prescribed) and not expired.

Compounding

- Remove caps from vials & Remove caps from vials tand disinfect stoppers.
- Reconstitute infliximab sterile water, directing the stream towards the side of the vial to minimize foaming.
- Roll the infliximab gently and continuously between both hands until it's completely dissolved.
- Check to ensure infliximab is completely dissolved.
- Withdraw the solution into the syringe, after injecting air into the vail. Remove air from the syringe.
- Inject infliximab into the 0.9% NaCl bag.
- Gently rock the bag back and forth to thoroughly mix the medication into the solution.

Administration

- Infuse the entire contents of the bag, as instructed don the product label.
- Infliximab infusion should begin within 3 hours of the reconstitution.
- The infusion must be administered over a period of no less than 2 hours.
- Infliximab must be infused via a 1.2 micronfilter.
- Note: The solution should be opalescent, colorless to light yellow and may develop a few translucent particles, as infliximab is a protein.

DO NOT SHAKE!!

Must use a 1.2-micron filter

Do not use if not fully dissolved or if opaque particles, discoloration, or other foreign particles are present.

Vedolizumab (Entyvio)

Adult Dosing: 300mg IV Week 0, 2, 6, then Q8wks

Supplies

- IV supplies to insert or access vascular access device.
- Medication bag (0.9% Sodium Chloride)
- Vedolizumab vial(s)
- Sterile water vial(s)
- 10mL syringe(s) with needle
- Antiseptic cleanser
- Gravity Tubing
- Prefilled saline syringes
- Heparin prefilled syringe (if indicated)

Prior to mixing

- Check vitals and request patient health history (illnesses).
- Insert/access intravenous catheter and ensure patency.
- Gather supplies.
- Ensure emergency medication is readily available (if prescribed) and not expired.

Compounding

- Remove caps from vials & disinfect stoppers.
- Reconstitute vedolizumab with sterile water, directing stream towards the side of the vial to minimize foaming.
- Gently swirl the vedolizumab for 15 seconds & allow the solution to sit for 20 minutes.
- If not completely dissolved, swirl vial and let it sit for 10 more minutes.
- Gently invert the vial 3 times prior to withdrawing the vedolizumab.
- Withdraw the solution into the syringe, after injecting air into the vial. Remove air from syringe.
- Inject the vedolizumab into the 0.9% NaCl bag.
- Gently rock the bag back and forth to thoroughly mix the medication into the solution.

Administration

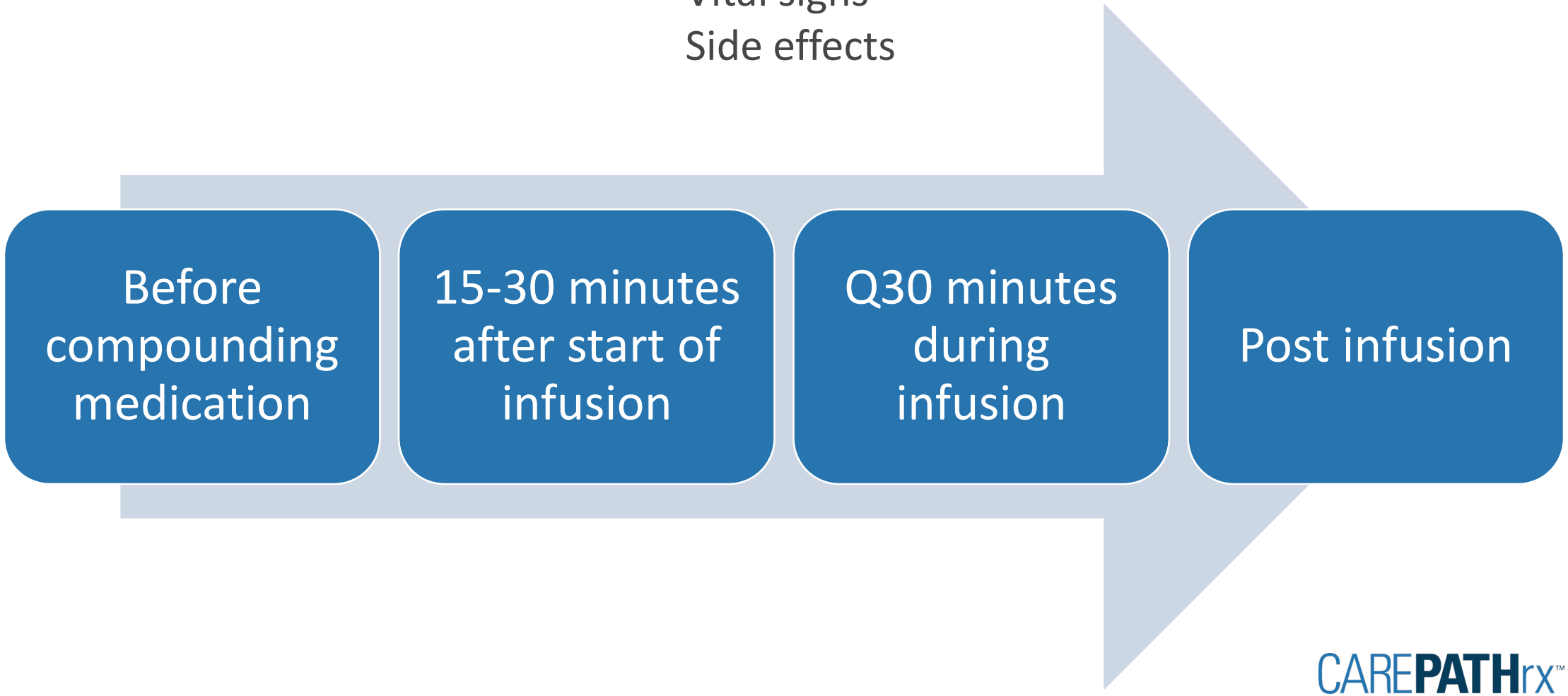
- Infuse the entire contents of the bag, as instructed on the product label, over 30 minutes.
- After infusion flush with 30ml of saline.
- Vedolizumab infusion should be administered within 4 hours of the reconstitution.
- Note: The solution should be clear and colorless to light brownish-yellow

DO NOT SHAKE!!

If not fully dissolved after a total of 30 minutes DO NOT USE.

Patient Monitoring

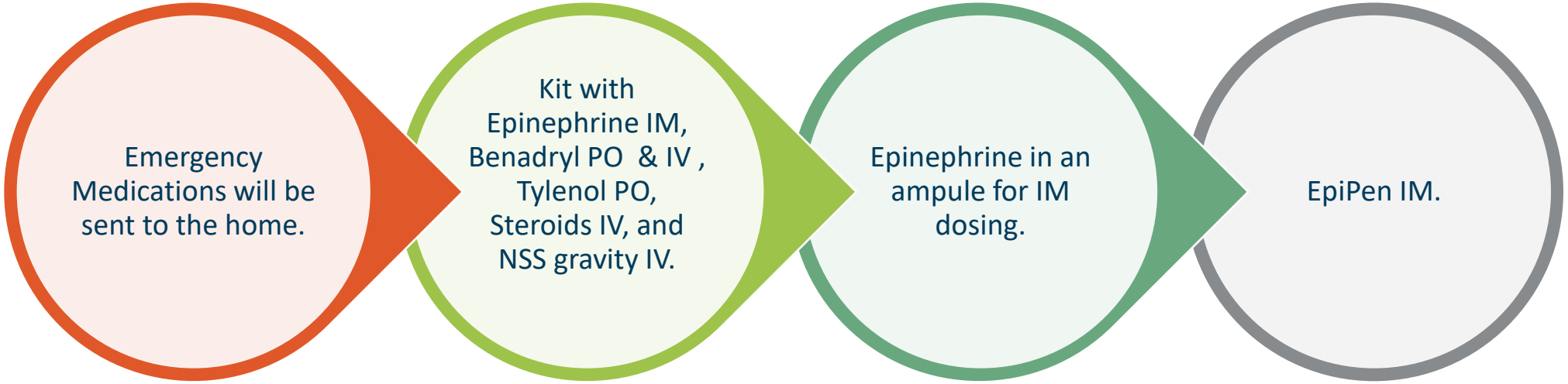
Vital signs
Side effects



CAREPATHrx™
Specialty Pharmacy & Infusion Solutions

Intolerance & Hypersensitivity Reactions

Hypersensitivity and anaphylactic reactions are rare, but emergency medications will be present in the home



CAREPATHrx™
Specialty Pharmacy & Infusion Solutions

Infusion Reactions

Mild Reaction	Moderate Reaction	Severe Reaction
• Itching • Flushing • Myalgia • Fever <38°C	• Chest Tightness • Hives • Hypertension • Tachycardia • Fever >38°C	• Bronchospasm • Angioedema • Hypotension

Often pretreat with Tylenol, hydrocortisone and/or antihistamine.

CAREPATHrx™
Specialty Pharmacy & Infusion Solutions

Mild Reaction

Itching | Flushing | Myalgia | Fever <38°C — Common

- Slow the infusion
- Initiate NSS infusion

- Diphenhydramine if ordered
- Acetaminophen if ordered

- Increase infusion rate as tolerated to complete infusion

CAREPATHrx™
Specialty Pharmacy & Infusion Solutions

Moderate Reaction

Chest Tightness | Hives | Hypertension | Tachycardia | Fever >38°C

↑ risk w/↑ exposure

- Stop the infusion
- Initiate NSS infusion

- Diphenhydramine if ordered
- Acetaminophen if ordered
- Methylprednisolone if ordered

- Resume infusion at 10ml/hr and increase rate as tolerated to complete infusion

CAREPATHrx™
Specialty Pharmacy & Infusion Solutions

Severe Reaction

Bronchospasm Angioedema Hypotension Rare

- Stop the infusion
- Call 911
- Place in supine position and elevate legs

- Epinephrine IM if ordered. May need to repeat Q5min times 3 doses
- Initiate NSS infusion at 500ml/hr
- Diphenhydramine IV if ordered Methylprednisolone IV if ordered

- May need to start CPR

CAREPATHrx™
Specialty Pharmacy & Infusion Solutions

Supplemental Product Labels

Pharmacy Name
Pharmacy Address
Pharmacy Phone Number

RX#: 15-0 FILL DATE: 11/22/2021

PRESCRIBER: Ordering Provider Name

Patient Name
Patient Address

WV 26169

CONTENTS: UNITS: 10
SODIUM CHLORIDE 0.9% 10ML SYRINGE (BD) 10 ML
DIRECTIONS:
FLUSH WITH 3ML 0.9% SODIUM CHLORIDE BEFORE AND AFTER IV DOSE ADMINISTRATION.
STORE AT ROOM TEMPERATURE.
^NO LAB DRAW FROM LINE UNLESS APPROVED BY PHYSICIAN~
DISCARD AFTER: 11/22/2022 FILLED BY: LKA100
FEDERAL LAW PROHIBITS THE TRANSFER OF THIS DRUG TO ANY PERSON OTHER THAN THE PRESCRIBED PATIENT.

CONTENTS: UNITS: 1
SOLU-MEDROL (PFIZER) 62.5 MG
ACETAMINOPHEN 325 MG TABLET (MAJOR) 650 MG
DIPHENHYDRAMINE 25MG CAPSULE (MAJOR) 50 MG
DIRECTIONS:
Administer acetaminophen 650mg orally prior to PRIVIGEN administration as premed.
Activate and infuse Methylprednisolone 62.5mg IV over 3-5 minutes prior to PRIVIGEN administration as premed.
Administer diphenhydramine 50mg capsule orally prior to PRIVIGEN administration as premed.
STORE AT ROOM TEMPERATURE.
^NO LAB DRAW FROM LINE UNLESS APPROVED BY PHYSICIAN~
DISCARD AFTER: 11/22/2022 FILLED BY: LKA100
FEDERAL LAW PROHIBITS THE TRANSFER OF THIS DRUG TO ANY PERSON OTHER THAN THE PRESCRIBED PATIENT.

CONTENTS:MAB-EMERGENCY MEDS UNITS:1
DIRECTIONS:
IN CASE OF ADVERSE DRUG REACTION:
Administer Acetaminophen 650mg ONCE. Administer Diphenhydramine 50mg (1ml) IV over 2-5 minutes ONCE or diphenhydramine 50mg capsule by mouth ONCE and activate and administer hydrocortisone 100mg IV ONCE. Epinephrine 0.5mg/0.5ml IM and may repeat ONCE in 5-15 minutes. If symptoms are rapidly progressing or continue NOTIFY PHYSICIAN

CAREPATHrx™
Specialty Pharmacy & Infusion Solutions

Biologic Takeaways

- Start IV before mixing medication.
- Ensure emergency medications are in the home and not expired.
- Refer to package insert for drug specific compounding, side effects, dosing and administration.
- Refer to product label for physician infusion instructions.
- Know how to activate EMS.
- Video link to How to give IM Epinephrine in Anaphylaxis Kit
  - https://youtu.be/GolInHBf0WM

CarepathRx Contacts:

nursingsupport@homeinfusion.com

Christie Fisher MSN, MBA, RN, CRNI, IgCN
National Director, Nursing
Cell: 412-295-7849

Thank you for participating!

Please reach out with questions or for information on additional training opportunities.