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.

Guselkumab (Tremfya) Clinical Guideline for Home Intravenous Therapy

Section: Clinical Guideline
Compliance: ACHC Infusion Pharmacy
Policy ID: CG016
Effective: 11/15/2024
Reviewed: 7/7/2025
Revised: 7/7/2025
Approved by, Title and Date Approved: Kathleen Patrick, President, 11/15/24, 7/7/25

I. BACKGROUND

Guselkumab (Tremfya) is a human immunoglobulin G1 (IgG1) monoclonal antibody that inhibits interleukin 23, specifically binding to the p19 subunit. The inhibition of interleukin 23 prevents the downstream release of pro-inflammatory cytokines involved in inflammatory and immune responses. Additionally, guselkumab also binds to CD64, a receptor on cells that produce interleukin 23. Guselkumab is indicated in adult patients for the treatment of moderate to severe plaque psoriasis, active psoriatic arthritis, moderate to severe ulcerative colitis, and moderate to severe Crohn's disease. The following outlines the procedures for servicing patients in need of outpatient guselkumab infusions at home.

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 guselkumab must include:

1. Drug
2. Dose
3. Route of administration
4. Frequency of administration
5. Emergency medications per protocol
6. Orders for pre-medications
7. Line care protocol
8. Routine lab monitoring, if applicable

D. Patients should be tested for tuberculosis (TB) prior to therapy initiation.

E. Prior to starting therapy, patients should be evaluated for need to administer age-appropriate vaccines and presence of active infection.

F. 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. Moderate to severe plaque psoriasis in adults- approved for subcutaneous (SC) injection
2. Active psoriatic arthritis in adults- approved for SC injection
3. Moderate to severe ulcerative colitis in adults- Intravenous (IV) induction and SC maintenance injections
4. Moderate to severe Crohn's disease in adults- Intravenous (IV) induction and SC maintenance injections

B. Dosing:

1. Moderate to Severe Ulcerative Colitis:
   a. Induction: 200 mg IV at week 0, week 4, and week 8
   b. Maintenance: 100 mg SC injection at week 16 and then every 8 weeks thereafter, or 200 mg SC injection at week 12 and every 4 weeks thereafter.

2. Moderate to Severe Crohn's disease:
   a. Induction: 200 mg IV at week 0, week 4, and week 8 OR 400 mg SC injection at week 0, week 4, and week 8.
   b. Maintenance: 100 mg administered by SC injection at Week 16, and every 8 weeks thereafter, or 200 mg administered by SC injection at Week 12, and every 4 weeks thereafter.

3. Other indications with SC administration alone are beyond the scope of this guideline.

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

C. Dose Adjustment:

1. No hepatic, renal, or weight dose adjustments.

D. Duration:

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

E. Contraindications:
1. Serious hypersensitivity reactions to guselkumab or to any of its excipients

F. Warnings and Precautions:

1. **Hypersensitivity reactions**: serious hypersensitivity reactions including anaphylaxis have been reported with post marketing use.
2. **Infections**: Guselkumab may increase the risk of infection. Treatment should not be initiated in patients with active infections until it is resolved or treated. If a serious infection develops, discontinue guselkumab until the infection
3. **Tuberculosis (TB):** Patients should be evaluated for TB infection prior to initiating therapy. Patients with latent TB should be treated prior to starting guselkumab.
4. **Hepatotoxicity:** drug-induced liver injury was reported in a clinical trial patient with Crohn's disease following three doses of a higher than the recommended induction regimen. This patient had an ALT of 18x the upper limit of normal (ULN), AST of 11x ULN, and total bilirubin of 2.4x ULN. Guselkumab was discontinued, and the liver test abnormalities resolved following administration of corticosteroids. In patients with Crohn's disease or ulcerative colitis, evaluate liver enzymes and bilirubin at baseline, for at least 16 weeks of treatment, and periodically thereafter according to routine patient management. Consider other treatment options in patients with evidence of acute liver disease or cirrhosis.
5. **Immunizations:** Patients should be brought up to date with all age-appropriate immunizations before initiating therapy. Live vaccines should not be given concurrently with guselkumab.
6. **Pregnancy and lactation**: There is a pregnancy registry that monitors pregnancy outcomes in women exposed to guselkumab during pregnancy. Patients should be encouraged to enroll in the registry by visiting www.mothertobaby.org/ongoing-study/tremfya-guselkumab, by calling 1-877-311-8972, or emailing MotherToBaby@health.ucsd.edu. Available data from literature, post-marketing reports, and ongoing pregnancy registry with guselkumab use in pregnant women are insufficient to establish a drug associated risk of major birth defects, miscarriage or other adverse maternal or fetal outcomes. Human IgG antibodies are known to cross the placental barrier; therefore, guselkumab may be transmitted from the mother to the developing fetus. There is no data on the presence of guselkumab in human milk, the effects on the breastfed infant, or the effects on milk production. Guselkumab was not detected in the milk of lactating monkeys. Endogenous maternal IgG and monoclonal antibodies are transferred into human milk. The effects of local gastrointestinal exposure and the extent of systemic exposure in the breastfed infant to guselkumab are unknown. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for guselkumab and any potential adverse effects on the breastfed infant from guselkumab or from the underlying maternal condition.

G. Pharmacokinetics

1. Absorption: Following the recommended intravenous induction dose regimen of guselkumab 200 mg at weeks 0,4, and 8, mean peak serum guselkumab concentration at week 8 was 68.3+/- 17.3mcg/mL in adults with ulcerative colitis
2. Volume of distribution at steady state in adult patients with ulcerative colitis was 10.1 L
3. Metabolism: Guselkumab is broken down into small peptide and amino acids via catabolic pathways
4. Elimination: Clearance in patients with ulcerative colitis was 0.531 L/day. Mean half life was approximately 17 days in patients with ulcerative colitis.

H. Adverse Reactions:

1. Upper respiratory infection (8.8%)

2. Arthralgia (4.3%)
3. Headache (4.6%)
4. Diarrhea (1.6%)
5. Gastroenteritis (1.3%)
6. Elevated liver enzymes (2.6%)
7. Hypersensitivity reactions

I. Drug Interactions:

1. Live vaccines: concurrent use of guselkumab and live vaccines may result in reduced effectiveness of immunization and increased risk of infection.
2. Biologics and immunosuppressants: may enhance immunosuppressive effect when combined.
3. Consult interaction database for patient specific assessment.

IV. ADMINISTRATIVE GUIDELINES

A. Administration: IV infusions should be given immediately after reconstitution and dilution. Complete

B. the infusion within 4 hours of preparation per current USP Immediate-Use Guidelines.

C. Administer guselkumab using an infusion set with an in-line or add-on **0.2-micron low protein binding filter**.

D. Do not co-administer other IV products in the same infusion line as guselkumab.

V. NURSING PROCEDURE

A. Supplies may include but are not limited to:

1. Alcohol Swabs
2. Gloves
3. Tape
4. IV access supplies as applicable
    a. Peripheral IV access supplies for patients requiring peripheral IV access
        1) IV start Kit
        2) Peripheral IV catheter (ex. 22 Gauge x1" and 24 Gauge x ¾")
        3) Extension set 8" with needless connector
    b. Port access supplies for patients with a port
        1) Port needle (ex. 22 Gauge x ¾ to 1" safe step)
        2) Needless connector
        3) Central line dressing change kit
5. IV Pole
6. IV administration set (flow regulator or gravity tubing) with in-line or add-on **0.2 micron filter**
7. Syringes (30 mL) with needles (20 G x 1")
8. Sharps container

B. Prescription items:

1. Guselkumab vial

2. 250 mL 0.9% sodium chloride stock bag
3. Standard flushes per protocol
4. Anaphylaxis kit per protocol

C. How Supplied: Guselkumab is a clear an colorless to light yellow solution supplied as 200mg/20mL (10mg/mL) single dose vial. (NDC: 57894-650-02)

D. Storage and Handling: Guselkumab is sterile and preservative free. Discard any unused portion. Store in the refrigerator at 2ºC to 8ºC (36ºF to 46ºF). Protect from light in original carton until time of use. Do not shake and do not freeze. Not made with natural rubber latex.

E. Compatibility: Compatible with 0.9% sodium chloride.

F. Procedures:

1. Explain the reasoning for visit and use of guselkumab.
2. Don gloves.
3. Assess for signs and symptoms of infection prior to establishing venous access and preparing medication. Notify ordering physician and pharmacist if signs or symptoms are present.
4. Establish venous access prior to preparation of drug.
5. Counsel patient on warnings, precautions, and potential side effects including but not limited to hypersensitivity reactions, risk of infection, headache, arthralgia, and diarrhea
6. Prepare Product:
    a. Withdraw 20 mL of 0.9% sodium chloride from 250 mL stock bag and discard.
    b. Withdraw 20 mL of guselkumab from the vial and add to the 0.9% sodium chloride bag for a final concentration of 0.8mg/mL. Gently mix the diluted solution. Discard the guselkumab vial with any excess solution.
    c. Visually inspect the diluted solution for particulate matter and discoloration before infusion.
    d. Use an infusion set with an in-line or add on **0.2-micron filter**.
7. Infusion Rate: Infuse over 60 minutes
8. 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. Tuberculosis (TB) screening
2. Complete all age-appropriate vaccinations as recommended by current immunization guidelines.
3. Baseline labs including liver enzymes

B. During therapy:

1. Signs/symptoms of infection
2. Signs of hypersensitivity reactions
3. Routine CMP and CBC

4. Disease progression and therapy efficacy: Assess for worsening symptoms including abdominal pain, cramps, changes in stool, changes in weight, and frequency of flares

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

REFERENCES:

Tremfya (guselkumab) [package insert]. Horsham, PA: Johnson and Johnson, Inc.; March 2025.

United States Pharmacopeia (USP). General Chapter, <797> Pharmaceutical Compounding—Sterile Preparations. (2023) USP-NF. Rockville, MD: United States Pharmacopeia. Accessed November 29, 2023.

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 <u>Anaphylaxis Kit Contents</u>.

You will need:

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

All other contents will not be needed.

Open the IM Epinephrine Bag

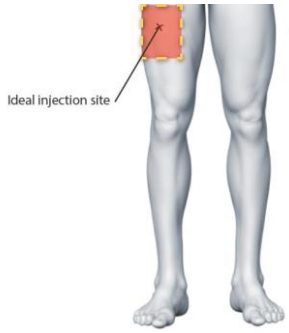
1. **Remove 1 of each item**
    a. 1 -syringe
    b. 1 – brown labeled filter needle (BD Filter Needle)- **for ampule use only**
    c. 1 – black labeled safety needle (Magellan Hypodermic Safety Needle 22G x 1”)
    d. 1 ampule of epinephrine

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.