Memorial Healthcare System

DENOSUMAB & BIOSIMILARS

PATIENT INFORMATION / REFERRAL STATUS

Referral Status: □ New Referral □ Updated Order □ Order Renewal **Date:** _____

Patient Name: _____ DOB: _____

ICD-10 Code: _____ ICD-10 Description/Diagnosis: _____

Allergies: □ NKDA Allergies: _____ Weight: _____ □ lbs/□ kg Height: _____

Patient Status: □ New to Therapy □ Continuing Therapy Last Treatment Date: _____ Next Due Date: _____

PROVIDER / PRACTICE INFORMATION

Ordering Provider: _____ Provider NPI: _____

Referring Practice Name: _____ Phone: _____ Fax: _____

Practice Address: _____ City: _____ State: _____ Zip: _____

Referral Coordinator Name: _____ Email: _____ Alternative Phone Number: _____

REFERRING PROVIDER COMMUNICATIONS

□ I have reviewed the prescribing information and medication guide for Prolia/Jubbonti/Stoboclo/Conexxence/Ospomyv/Bosaya/Bildyos (denosumab/denosumab-bbdz,-bmwo,-bnht,-dssb,-kyqq,-nxxp).

- Pre-existing hypocalcemia must be corrected prior to initiating therapy. It's recommended for patients to take calcium 1000 mg daily and at least 400 IU vitamin D daily.
- Denosumab causes fetal harm when administered to a pregnant woman. Rule out pregnancy prior to therapy in women of childbearing potential.
- Before initiating therapy, evaluate for the presence of chronic kidney disease mineral and bone disorder with intact parathyroid hormone, serum calcium, 25(OH) vitamin D, and 1,25(OH)2 vitamin D; specially in patients with advanced chronic kidney disease, including dialysis patients.
- REMS Product in Patients with Advanced Chronic Kidney Disease (aCKD). Patients with aCKD [i.e., eGFR < 30 mL/min/1.73 m2] including dialysis-dependent patients are at greater risk for severe hypocalcemia following denosumab administration. The presence of underlying CKD-mineral bone disorder (CKD-MBD, renal osteodystrophy) markedly increases the risk of hypocalcemia.

a. Monitor serum calcium weekly for 1 month, then monthly.
b. Provide and review with patient the medication guide.
c. Educate patient how to recognize symptoms of hypocalcemia. Instruct patients to seek immediate medical attention if symptoms occur.
d. Educate patient about the importance of maintaining serum calcium levels with adequate calcium and vitamin D supplementation.

- Patient may be at risk of developing medication-related osteonecrosis of the jaw (MRONJ). Assess patient for recent tooth extraction or other invasive dental procedures while on therapy and determine risk vs benefit of starting or continuing treatment.
- Atypical femur fractures may occur in patients receiving denosumab. Instruct patient to report new or unusual thigh, hip, or groin pain while on therapy.

NURSING PROTOCOL COMMUNICATIONS

☒ Provide nursing care, vital signs, monitoring according to Memorial Outpatient Procedures. Establish/maintain IV access and administer medication as ordered. Remove peripheral IV access after infusion completion if applicable. Follow infusion-related/hypersensitivity reactions management according to MHS Outpatient Adverse Reaction Protocol available for review on at mhs.net/services/pharmacy/infusion-services/outpatient-infusion.

☒ Discharge/Follow-up instructions according to Memorial Outpatient Procedures.

LABORATORY ORDERS

□ ***Pregnancy, Urine for females of childbearing potential who have not undergone a hysterectomy:***
□ Once □ Every Visit □ Every ____ months

□ ***CBC with Diff:*** □ Once □ Every Visit □ Every ____ months

□ ***Comprehensive Metabolic Panel:*** □ Once □ Every Visit □ Every ____ months □ Weekly x4 then Monthly

□ ***CRP:*** □ Once □ Every Visit □ Every ____ months

□ ***Vitamin D 25 hydroxy:*** □ Once □ Every Visit □ Every ____ months

□ ***Intact parathyroid hormone:*** □ Once □ Every Visit □ Every ____ months

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PRE-MEDICATION ORDERS (30-60 Minutes Prior to Therapy)

□ Acetaminophen (Tylenol) 650 mg PO

□ Diphenhydramine (Benadryl) □ 25 mg □ 50 mg PO **OR** □ Cetirizine (Zyrtec) or Loratadine (Claritin) 10 mg PO

□ Dexamethasone (Decadron) □ 8 mg □ 20 mg PO

□ Other: _____ Dose: _____ Route: _____ Frequency/Timing: _____

THERAPY PLAN

Select Product:

□ MHS Pharmacy to select product based on payor requirements, product availability, and indication.

OR Do Not Substitute and use product below (Check One):

□ Denosumab (Prolia)
□ Denosumab-bmwo (Stoboclo)
□ Denosumab-dssb (Ospomyv)
□ Denosumab-nxxp (Bildyos)
□ Denosumab-bbdz (Jubbonti)
□ Denosumab-bnht (Conexxence)
□ Denosumab-kyqq (Bosaya)

Dose: 60 mg/mL

Frequency: □ Once □ Every 6 months

Route: □ IV ☒ SQ □ IM

Additional Administration Instructions:

REMS: Patients with advanced CKD (eGFR <30 mL/min/1.73 m^2), including those on dialysis, are at risk for severe hypocalcemia post-administration. Restricted to outpatient use. Monitor serum calcium weekly for 1 month, then monthly. Provide and review the medication guide, including symptoms of hypocalcemia, and instruct patients to seek immediate medical attention if symptoms occur.

Note to Pharmacy/Comments:

_____

_____

Refills: □ Zero □ for 12 months □ Other:_____

(if not indicated, order will expire one year from date signed)

_____	_____	_____
Provider Name (Print)	***Provider Signature***	***Date***

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Adverse Reaction Management Protocol (Adult)

Observe patient for infusion related and hypersensitivity reactions such as fever, chills, rigors, pruritus, rash, cough, sneezing, throat irritation, nausea, vomiting.

If reaction occurs:

- Stop infusion and assess patient.
- Maintain or establish vascular access if needed
- **Administer emergency medication(s) according to symptoms:**

☒ Acetaminophen 650 mg PO once PRN headache, pain, fever >100.4F, chills or rigors.

☒ Diphenhydramine 50 mg IV once PRN itching, allergies, infusion reaction, hives, pruritic and other nonspecific symptoms of allergic reaction **OR**

☒ Diphenhydramine 50 mg IM once PRN itching, allergies, infusion reaction, hives, pruritic and other nonspecific symptoms of allergic reaction (if no IV access)

☒ Dexamethasone 10 mg IV once PRN shortness of breath or wheezing **OR**

☒ Dexamethasone 10 mg IM once PRN shortness of breath or wheezing (if no IV access)

☒ Ondansetron 4 mg IV once PRN nausea, vomiting **OR**

☒ Ondansetron 4 mg IM once PRN nausea, vomiting (if no IV access)

- May re-start therapy if appropriate when symptoms resolve. Resume infusion at 50% of the previous rate and increase per manufacturer's guidelines.

If a severe allergic/anaphylactic reaction occurs

- Symptoms are rapidly progressing or continuing after administration of PRN medications and/or signs and symptoms of severe allergic/anaphylactic reaction (angioedema, swelling of the mouth, tongue, lips, or airway, dyspnea, bronchospasm with or without hypotension or hypertension)

☒ Notify the Rapid Response / Rescue Alert Team / Blue Alert / 911.

☒ Initiate BLS/ Cardiopulmonary resuscitation if necessary.

☒ Administer Epinephrine 0.3 mg intramuscularly, every 5 MIN PRN rapidly progressing or continuing after administration of PRN medication or signs and symptoms of severe allergic/anaphylactic reaction. Administer every 5-15 minutes as needed preferably in the outer thigh.

☒ Place the patient in a recumbent position, elevate lower extremities.

☒ Continuously monitor vital signs (blood pressure, pulse oximetry, and heart rate).

☒ Contact and notify the referring provider on the day of occurrence once patient is stabilized.

☒ Document reaction in the medical record and complete an incident report once patient is stabilized.