infusioncare
OF COMMUNITY CARE PHYSICIANS

PROLIA INFORMED CONSENT FORM

Your physician has recommended a PROLIA Injection for the treatment. Before agreeing to this treatment, it is important that you read and understand the following explanation of the PROLIA Injection Treatment Process. This statement will describe the procedure, benefits, discomforts, risks and precautions.

PROLIA® (denosumab) INJECTION FOR OSTEOPOROSIS indicated for:

- Treatment of postmenopausal women with osteoporosis who are at high risk for fracture.
- Treatment to increase bone mass in men with osteoporosis at high risk for fracture.
- Treatment to increase bone mass in men at high risk for fracture receiving androgen deprivation therapy for non-metastatic prostate cancer.
- Treatment to increase bone mass in women at high risk for fracture receiving adjuvant aromatase inhibitor therapy for breast cancer.

Patients receiving PROLIA® should continue to take calcium and vitamin D. Calcium and vitamin D intake is important in women with osteoporosis and the current recommended daily intake of calcium is 1,200 mg and vitamin D is 400-800 IU daily.

The recommended dose of 60 mg of PROLIA® is available in a 1-ml subcutaneous injection. Medications given subcutaneously are administered with a smaller sized needle, into the fatty tissue just below your skin. PROLIA® injections should be given every 6 months.

Osteonecrosis of the jaw has been reported in patients treated with PROLIA. Most cases have been in people suffering from cancer undergoing dental procedures, but some have occurred in patients with osteoporosis, or other diagnoses. Known risk factors for osteonecrosis include a diagnosis of cancer, concomitant therapies (chemotherapy, radiotherapy, corticosteroids), and co-morbid disorders (anemias, coagulopathy, infection, pre-existing dental disease).

Potential adverse reactions, all of which are uncommon, include:

- Bone, joint or muscle pain
- Constant jaw pain, including burning or cramping
- Eye inflammation, pain, or vision change
- Impairment of kidney function - very uncommon unless baseline kidney function is abnormal.
- Low blood calcium level - everyone taking PROLIA should be receiving calcium and vitamin D supplements to minimize this risk unless contraindicated.
- Allergic reaction
- Osteonecrosis of the jaw - if you have oral pain, loosening of the teeth, or an infection of the

mouth that will not heal, please alert your doctor.

Prior to receiving PROLIA® injections, please tell your physician or nurse if you have or have had in the past (please initial)

Prior to using PROLIA, please tell your physician or nurse if you (please initial):

_____ Kidney problems

_____ History of low blood calcium level

_____ Pregnant or breast feeding

_____ Not able to take daily calcium and vitamin D supplements

_____ Parathyroid or thyroid surgery

_____ Malabsorption syndrome

_____ Section of your intestine removed

_____ Planned dental surgery

_____ Any Fever or Current Signs/Symptoms of an Infection

_____ Any Acute Cut, Wound or Rash

I understand all possible side effects from this medication may not have been completely identified and as new information becomes available I will be notified.

I have had the opportunity to fully read, understand and discuss this consent form with my physician and the nurses. By signing this consent, I am agreeing to treatment with PROLIA.

_____	_____
Patient's Name	Witness' Name
_____	_____
Patient's Signature	Witness' Signature
_____	_____
Date	Date