infusioncare
OF COMMUNITY CARE PHYSICIANS

ZOLEDRONIC ACID/RECLAST INFORMED CONSENT FORM

Your physician has recommended ZOLEDRONIC ACID (RECLAST®) intravenous injection for the treatment. Before agreeing to this treatment, it is important that you read and understand the following explanation of the ZOLEDRONIC ACID infusion process. This statement will describe the procedure, benefits, discomforts, risks and precautions.

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ZOLEDRONIC ACID is in the class of medications termed "bisphosphonates". All bisphosphonates slow down bone breakdown (resorption). As bone is being continuously remodeled, formation and breakdown ongoing throughout life, medications which inhibit bone breakdown can lead to an increase in bone mass. That is the rationale for bisphosphonate therapy.

We are employing ZOLEDRONIC ACID only to those individuals with established osteoporosis (by DEXA scan and/or a history of fractures), in patients whom oral bisphosphonates are contraindicated by gastrointestinal disease. ZOLEDRONIC ACID is not a hormone and can be administered to both men and women.

Osteonecrosis of the jaw has been reported in patients treated with bisphosphonates. 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). Most reported cases have been in patients treated with bisphosphonates intravenously but some have been in patients treated orally. Patients contemplating major dental procedures may have increased risk and should inform their dentist.

Patients receiving ZOLEDRONIC ACID *should continue* to take calcium and vitamin D throughout the course of bisphosphonate therapy.

ZOLEDRONIC ACID is given as a **5 mg** intravenous injection, administered every **year**.

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 ZOLEDRONIC ACID should be receiving calcium and vitamin D supplements to minimize this risk unless contraindicated.
- Allergic reaction

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- 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 using ZOLEDRONIC ACID, 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 ZOLEDRONIC ACID.

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