## Prescribing Protocol

### Title
Adjuvant Zoledronic Acid for Early/Locally Advanced Breast Cancer

### Areas where Protocol/Guideline applicable e.g. District, Hospital, ITU, Ward
SESLHD Oncology Centres

### Areas where Protocol/Guideline not applicable
Non-oncology areas

### Authorised Prescribers
Medical Oncologists

### Indication for use
Minimisation of skeletal events and premature osteoporosis in post-menopausal women with early or locally advanced breast cancer

### Clinical condition
Adjuvant therapy for post-menopausal women with early or locally advanced breast cancer

### Contra-indications
- Osteonecrosis of the jaw
- Previous anaphylaxis to zoledronic acid or its excipients
- Pregnancy or breastfeeding

### Precautions
Hypocalcaemia - corrected calcium level below the normal range of 2.15 to 2.65 mmol per litre.
Use not recommended in patients with severe renal impairment (CrCl < 30mL/min)

### Place in Therapy
First line therapy after or in conjunction with standard adjuvant therapy (surgery, chemotherapy, radiotherapy and hormonal manipulation)

### Dosage
4mg intravenously every 6 months for 3 years

#### Dosing in renal impairment:
- 3.5mg – CrCl 50-60mL/min
- 3.3mg – CrCl 40-49mL/min
- 3mg – CrCl 30-39mL/min

### Duration of therapy
3 years (6 doses)

### Important Drug Interactions
N/A

### Administration instructions
Administer in 100mL Sodium Chloride 0.9% over 15 mins
Prescribing Protocol SESLHDPR/664  
Zoledronic Acid for early / locally advanced  
Breast cancer

| Monitoring requirements | Blood monitoring requirements:  
Before starting therapy, ensure Vitamin D levels are adequate.  
To check serum creatinine, calcium, magnesium and phosphate within 7 days before zoledronic acid infusion.  
Zoledronic acid can cause hypocalcaemia and therefore calcium levels need to be monitored throughout treatment. A patient’s corrected calcium level must be measured within the 7 days prior to zoledronic acid administration. If the corrected calcium is not within range 2.15 to 2.65 mmol per litre (unless otherwise stated by Medical Officer), zoledronic acid must not be administered the relevant MO.  
The MO is to advise:  
- whether the dose is to be administered or withheld  
- what dose of calcium supplements the patient needs to take to increase their calcium levels  
- when repeat blood test should be taken  
- a revised date for administration of the dose  

All patients will have ongoing clinical review with their medical oncologists for breast cancer surveillance (annual mammogram and ultrasound and 2-3 yearly bone mineral density) |

| Management of complications | Osteonecrosis of the Jaw (ONJ) – this is a rare but serious side effect involving the exposure of the jaw bone through lesions in the gingiva which do not heal. It can occur spontaneously but is most common following dental procedures. Symptoms can include pain, numbness, swelling, loose teeth, exposed bone and non-healing extraction sockets. Patient should have a full dental check-up before treatment commences and regularly throughout duration of treatment as advised by dentist and oncologist  
Supplementation of electrolyte deficiencies as necessary  
Flu like symptoms may occur in the days following the infusion, paracetamol can be used on a as required basis to mitigate this |
This protocol is consistent with guidelines established by American Society of Clinical Oncology (ASCO)¹ and European Consensus Panel² which is to offer adjuvant bisphosphonates in postmenopausal women with moderate to high risk of breast cancer recurrence who are receiving any systemic adjuvant therapy.

In the meta-analysis conducted by EBCTCG in 2015³, among postmenopausal women, bisphosphonate treatment resulted in statistically significant reductions in bone recurrence (6.6 versus 8.8 percent), fracture rates (0.1 versus 10.3 percent), breast cancer mortality (14.7 versus 18.0 percent) and overall survival (OS; 21.1 versus 23.5 percent).