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1. Rationale

The purpose of this Clinical Protocol is to provide a guiding framework for Hospital at the Home service Medical Practitioners and clinical staff.

2. Scope

The Clinical Protocol applies Nationally for HATH clients treated with Zoledronic Acid.



3. Acceptance to HATH Criteria and Pathway

RED Unacceptable for community admission to HATH Refer to ED/ Inpatient management. (May become suitable for HATH after ED or inpatient stabilisation)	 Previous hypersensitivity reaction to any Bisphosphonate. Current or recent Uveitis. Active dental problems likely to require invasive dental procedure within the next 3 months Hypocalcaemia Vitamin D < 50 nmol/L Dehydration. Creatinine clearance less than 35 mL/min. Patient unable to access zoledronic acid on the Pharmaceutical Benefit Scheme or other subsidised source.
ORANGE Requires discussion with prior to acceptance.	 Administration less frequently than 12 monthly Patients being treated for hypercalcaemia may need to be hydrated prior to and following infusion with normal saline 0.9%.
GREEN Accepted for HATH [Insert Text]	 There are four required inclusion criteria: The patient's medical condition has been assessed as stable The patient has a clear diagnosis and prognosis and is at a low risk of deterioration The referrer has discussed the risks and benefits of bisphosphonate treatment and The patient meets at least one of the criteria outlined below: Confirmed diagnosis of osteoporosis in post menopausal women and men aged above 70 with a bone mineral density (BMD) T score – 3.0 or less

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or
 Patients over 50 years that have had minimal trauma fracture with or without BMD abnormality
or
 Receiving steroids > 7.5mg/day over >3 months and T score -1.5 or less
or
 Confirmed diagnosis of Paget's Disease of bone and clinically active disease with Bone Turnover Abnormalities Bone Pain Fractures
or
 Prevention of skeletal related events in palliative patients
or
Hypercalcaemia of malignancy.

4. Pathology Work Up

- Bloods for U&E, calcium, magnesium, phosphate and Vitamin D.
- Calculation of creatinine clearance (Cockcroft Gault formula), prior to administration of dose.

5. General Management

Intravenous zoledronic acid can cause transient influenza-like symptoms. This most often occurs after the first dose and is less likely to occur with subsequent doses. To reduce the severity of the reaction, advise patients to take paracetamol before and for several days after the infusion.



Note that Zoledronic acid can cause hypocalcaemia, particularly in patients with risk factors for hypocalcaemia such as

- vitamin D deficiency,
- kidney disease or
- a malabsorption disorder.

Before the first dose, measure kidney function, serum corrected calcium concentration and serum 25-hydroxyvitamin D concentration.

In patients at risk of hypocalcaemia, these parameters should also be measured before each subsequent dose.

Intravenous administration of zoledronic acid is safe provided that:

- serum 25-hydroxyvitamin D concentration is greater than 50 nmol/L
- serum calcium concentration corrected for albumin is in the normal range (2.10 to 2.60 mmol/L)
- estimated glomerular filtration rate (eGFR) is greater than 35 mL/min/1.73 m²
- the patient is well hydrated.

6. Medical Management / Treatment Plan

- Access pathology results and ensure creatinine clearance is calculated prior to infusion.
- Collaborate with governing doctor regarding the abnormal pathology results.
- Collaborate with patient re prescription and delivery/availability of drug and suitable time/day for the administration of the infusion.
- Ensure the patient is well hydrated (unless chronic cardiac failure/overload concerns), 2 glasses of water prior to the infusion and 6-8 glasses over the next 24 hour period. Patients being treated for hypercalcaemia may need to be hydrated prior to and following infusion with normal saline 0.9%. Discuss with medical governance prior to infusion.
- Initiate intravenous access and commence infusion as prescribed.



- Recommended zoledronic acid infusion rate is usually over 30 mins
 - However, if the creatinine clearance less than 45mls/min or the patient is over 70 years of age the zoledronic acid infusion rate should be over 45 minutes.
- Paracetamol 1g qid or Paracetamol Osteo tds for 3 days is recommended post infusion.
- 7. Medical Governance
- The client must have access to medical governance support for the duration of the infusion
- Primary medical governance can be by referring medical specialists, credentialed referring GPs or by Silver Chain medical staff.
- Care delivery is planned and provided in consultation with the client, medical officer/specialist holding medical governance and nursing staff. Where the primary medical governor is unavailable a Silver Chain medical officer will provide the medical governance.
- In the instance when a client's condition deteriorates the Silver Chain medical officer or nursing staff can confer with a hospital specialist colleague or an emergency department medical officer.
- The ED is not the primary escalation point unless it is an emergency
- 8. Discharge Planning
- Ensure the client has an appointment arranged with own General Practitioner (GP) prior to discharge to ensure continuity of care.
- Ensure discharge summary has highlighted the key clinical concerns/risks you wish to hand over
- Fax client discharge summary to GP.

9. Supporting Documents

Silver Chain Group documents that directly relate to and inform this Clinical Protocol are available with this document in the Policy Document Management System (PDMS).

Other documents that directly relate to and inform this Clinical Protocol are as follows:



- Therapeutic Guidelines, Antiresorptive Drugs for Osteoporosis, amended December 2019, eTG March 2021 Edition https://tgldcdp-tg-org-au.silverchain.idm.oclc.org/viewTopic?topicfile=osteoporosisminimal-trauma-fracture&guidelineName=Bone and Metabolism#toc_d1e84
- Zoledonic Acid Drug information available from <u>www.ebs.tga.gov.au</u>

10. Document Details

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Document Type	CP – Clinical Protocol	
Consumer Participation	Yes Not Applicable	
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Periodic Review	36 months	

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