Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

**PRESCRIBER**

Name: .....

Ward: .....

**PATIENT:**

Name: .....

NHI: .....

## Zoledronic acid Inj 5 mg per 100 ml, vial

**INITIATION – Inherited bone fragility disorders**

**Prerequisites** (tick box where appropriate)

- ○ Prescribed by, or recommended by any specialist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

**and**

- ○ Patient has been diagnosed with an inherited bone fragility disorder (e.g. osteogenesis imperfecta)

**INITIATION – Osteoporosis**

Re-assessment required after 3 doses

**Prerequisites** (tick boxes where appropriate)

- ○ Prescribed by, or recommended by any specialist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

**and**

- ○ History of one significant osteoporotic fracture demonstrated radiologically and documented bone mineral density (BMD) greater than or equal to 2.5 standard deviations below the mean normal value in young adults (i.e. T-Score less than or equal to -2.5) (see Note)

**or**

- ○ History of one significant osteoporotic fracture demonstrated radiologically, and either the patient is elderly, or densitometry scanning cannot be performed because of major logistical, technical or pathophysiological reasons. It is unlikely that this provision would apply to many patients under 75 years of age

**or**

- ○ History of two significant osteoporotic fractures demonstrated radiologically

**or**

- ○ Documented T-Score greater than or equal to -3.0 (see Note)

**or**

- ○ A 10-year risk of hip fracture greater than or equal to 3%, calculated using a published risk assessment algorithm (e.g. FRAX or Garvan) which incorporates BMD measurements (see Note)

**or**

- ○ Patient has had a Special Authority approval for alendronate (Underlying cause - Osteoporosis) prior to 1 February 2019 or has had a Special Authority approval for raloxifene

**and**

- ○ The patient will not be prescribed more than 5 mg of zoledronic acid in a 12-month period

**INITIATION – glucocorticosteroid therapy**

Re-assessment required after 12 months

**Prerequisites** (tick boxes where appropriate)

- ○ Prescribed by, or recommended by any specialist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

**and**

- ○ The patient is receiving systemic glucocorticosteroid therapy (greater than or equal to 5 mg per day prednisone equivalents) and has already received or is expected to receive therapy for at least three months

**and**

- ○ The patient has documented BMD greater than or equal to 1.5 standard deviations below the mean normal value in young adults (i.e. T-Score less than or equal to -1.5) (see Note)

**or**

- ○ The patient has a history of one significant osteoporotic fracture demonstrated radiologically

**or**

- ○ The patient has had a Special Authority approval for alendronate (Underlying cause - glucocorticosteroid therapy) prior to 1 February 2019 or has had a Special Authority approval for raloxifene

**and**

- ○ The patient will not be prescribed more than 5 mg of zoledronic acid in the 12-month approval period

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

**PRESCRIBER**

Name: .....

Ward: .....

**PATIENT:**

Name: .....

NHI: .....

## Zoledronic acid Inj 5 mg per 100 ml, vial *- continued*

**CONTINUATION – glucocorticosteroid therapy**
Re-assessment required after 12 months
**Prerequisites** (tick boxes where appropriate)

- ○ Prescribed by, or recommended by any specialist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

**and**

- ○ The patient is continuing systemic glucocorticosteriod therapy (greater than or equal to 5 mg per day prednisone equivalents)

**and**

- ○ The patient will not be prescribed more than 5 mg of zoledronic acid in the 12-month approval period

**INITIATION – Paget's disease**
Re-assessment required after 12 months
**Prerequisites** (tick boxes where appropriate)

- ○ Prescribed by, or recommended by any specialist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

**and**

- ○ Paget's disease

**and**

- ○ Bone or articular pain

**or**

- ○ Bone deformity

**or**

- ○ Bone, articular or neurological complications

**or**

- ○ Asymptomatic disease, but risk of complications

**or**

- ○ Preparation for orthopaedic surgery

**and**

- ○ The patient will not be prescribed more than 5 mg of zoledronic acid in the 12-month approval period

**CONTINUATION – Paget's disease**
Re-assessment required after 12 months
**Prerequisites** (tick boxes where appropriate)

- ○ Prescribed by, or recommended by any specialist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

**and**

- ○ The patient has relapsed (based on increases in serum alkaline phosphatase)

**or**

- ○ The patient's serum alkaline phosphatase has not normalised following previous treatment with zoledronic acid

**or**

- ○ Symptomatic disease (prescriber determined)

**and**

- ○ The patient will not be prescribed more than 5 mg of zoledronic acid in the 12-month approval period

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

**PRESCRIBER**

Name: .....

Ward: .....

**PATIENT:**

Name: .....

NHI: .....

## Zoledronic acid Inj 5 mg per 100 ml, vial *- continued*

**INITIATION – spinal cord injury***
Re-assessment required after 12 months
**Prerequisites** (tick boxes where appropriate)

- ❍ Patient has experienced an acute traumatic spinal cord injury in the last six months

**and**

- ❍ Patient is being managed by a specialist spinal acute care and rehabilitation unit

**and**

- ❍ The patient will not be prescribed more than 5 mg of zoledronic acid in a 12-month period

Note: Indications marked with * are unapproved indications.

**CONTINUATION – spinal cord injury***
Re-assessment required after 6 months
**Prerequisites** (tick boxes where appropriate)

- ❍ The patient will not be prescribed more than 5 mg of zoledronic acid in a 12-month period

**and**

- ❍ The patient has not received more than two doses of zoledronic acid for this indication

Note: The patient must not have had more than 1 prior approval. No further renewals will be subsidised. A maximum of 2 vials of zoledronic acid treatment for spinal cord injury will be subsidised. Indications marked with * are unapproved indications.

Note:

a) BMD (including BMD used to derive T-Score) must be measured using dual-energy x-ray absorptiometry (DXA). Quantitative ultrasound and quantitative computed tomography (QCT) are not acceptable.

b) Evidence suggests that patients aged 75 years and over who have a history of significant osteoporotic fracture demonstrated radiologically are very likely to have a T-Score less than or equal to -2.5 and, therefore, do not require BMD measurement for treatment with bisphosphonates.

c) Osteoporotic fractures are the incident events for severe (established) osteoporosis and can be defined using the WHO definitions of osteoporosis and fragility fracture. The WHO defines severe (established) osteoporosis as a T-score below -2.5 with one or more associated fragility fractures. Fragility fractures are fractures that occur as a result of mechanical forces that would not ordinarily cause fracture (minimal trauma). The WHO has quantified this as forces equivalent to a fall from a standing height or less.

d) A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.



I confirm that the above details are correct:

Signed: ..... Date: .....