

APPLICANT (stamp or sticker acceptable) **PATIENT NHI:** **REFERRER** Reg No:

Reg No: First Names: First Names:

Name: Surname: Surname:

Address: DOB: Address:

..... Address:

.....

Fax Number: Fax Number:

Zoledronic acid inj 0.05 mg per ml, 100 ml

Initial application — Paget's disease

Applications from any relevant practitioner. Approvals valid for 1 year.

Prerequisites(tick boxes where appropriate)

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

Initial application — Underlying cause - Osteoporosis

Applications from any relevant practitioner. Approvals valid without further renewal unless notified.

Prerequisites(tick boxes where appropriate)

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 less 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

I confirm the above details are correct and that in signing this form I understand I may be audited.

Signed: Date:

Post application to Ministry of Health, Private Bag 3015, Wanganui – email: customerservice@health.govt.nz

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Zoledronic acid inj 0.05 mg per ml, 100 ml - continued

Initial application — Underlying cause - glucocorticosteroid therapy

Applications from any relevant practitioner. Approvals valid for 1 year.

Prerequisites(tick boxes where appropriate)

<input type="checkbox"/>	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	
<input type="checkbox"/>	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	
<input type="checkbox"/>	The patient has a history of one significant osteoporotic fracture demonstrated radiologically
or	
<input type="checkbox"/>	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	
<input type="checkbox"/>	The patient will not be prescribed more than 5 mg of zoledronic acid in the 12-month approval period

Renewal — Paget's disease

Current approval Number (if known):.....

Applications from any relevant practitioner. Approvals valid for 1 year.

The patient must not have had more than 1 prior approval in the last 12 months.

Prerequisites(tick boxes where appropriate)

<input type="checkbox"/>	The patient has relapsed (based on increases in serum alkaline phosphatase)
or	
<input type="checkbox"/>	The patient's serum alkaline phosphatase has not normalised following previous treatment with zoledronic acid
or	
<input type="checkbox"/>	Symptomatic disease (prescriber determined)
and	
<input type="checkbox"/>	The patient will not be prescribed more than 5 mg of zoledronic acid in the 12-month approval period

Renewal — Underlying cause was, and remains, glucocorticosteroid therapy

Current approval Number (if known):.....

Applications from any relevant practitioner. Approvals valid for 1 year.

The patient must not have had more than 1 prior approval in the last 12 months.

Prerequisites(tick boxes where appropriate)

<input type="checkbox"/>	The patient is continuing systemic glucocorticosteroid therapy (greater than or equal to 5 mg per day prednisone equivalents)
and	
<input type="checkbox"/>	The patient will not be prescribed more than 5 mg of zoledronic acid in the 12-month approval period

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Zoledronic acid inj 0.05 mg per ml, 100 ml - continued

Renewal — Underlying cause was glucocorticosteroid therapy but patient now meets the 'Underlying cause - osteoporosis' criteria

Current approval Number (if known):.....

Applications from any relevant practitioner. Approvals valid without further renewal unless notified.

Prerequisites(tick boxes where appropriate)

- 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 less 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
- The patient has had a Special Authority approval for alendronate (Underlying was glucocorticosteroid therapy but patient now meets the 'Underlying cause - Osteoporosis' criteria) 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

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.

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