Ministry of Health
Phone 0800 243 666

APPLICATION FOR SUBSIDY BY SPECIAL AUTHORITY

Form SA1035
January 2011

APPLICANT (stamp or sticker acceptable)

Reg No: .....

Name: .....

Address: .....

.....

.....

Fax Number: .....

PATIENT NHI: .....

First Names: .....

Surname: .....

DOB: .....

Address: .....

.....

.....

REFERRER Reg No: .....

First Names: .....

Surname: .....

Address: .....

.....

.....

Fax Number: .....

Zoledronic acid

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 one infusion 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) ≥ 2.5 standard deviations below the mean normal value in young adults (i.e. T-Score ≤ -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 ≤ -3.0 (see Note)

or

☐ A 10-year risk of hip fracture ≥ 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)

and

☐ The patient will not be prescribed more than one infusion in a 12-month period

Use next page for: Initial application - Underlying cause - glucocorticosteroid therapy, Renewal - Paget's disease, Renewal - Underlying cause was, and remains, glucocorticosteroid therapy and Renewal - Underlying cause was glucocorticosteroid therapy but patient now meets the 'Underlying cause - osteoporosis' criteria

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 – Fax: 0800 100 131

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Surname: .....

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.....

.....

Fax Number: .....

Zoledronic acid - continued

INITIAL APPLICATION - Underlying cause - glucocorticosteroid therapy
Applications from any relevant practitioner. Approvals valid for 1 year.

Prerequisites (tick boxes where appropriate)

☐ The patient is receiving systemic glucocorticosteriod therapy (≥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 ≥ 1.5 standard deviations below the mean normal value in young adults (i.e. T-Score ≤ -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)

and

☐ The patient will not be prescribed more than one infusion 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 have had no more than 1 prior approval in the last 12 months

Prerequisites (tick boxes where appropriate)

☐ 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 one infusion 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 have had no more than 1 prior approval in the last 12 months

Prerequisites (tick boxes where appropriate)

☐ The patient is continuing systemic glucocorticosteriod therapy (≥5 mg per day prednisone equivalents)

and

☐ The patient will not be prescribed more than one infusion in the 12-month approval period

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.

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Reg No:	First Names:	First Names: .....
Name:	Surname:	Surname: .....
Address:	DOB:	Address: .....
.....	Address:	.....
.....	.....	.....
Fax Number:	.....	Fax Number: .....

Prerequisites (tick boxes where appropriate)

- ☐ History of one significant osteoporotic fracture demonstrated radiologically and documented bone mineral density (BMD) ≥ 2.5 standard deviations below the mean normal value in young adults (i.e. T-Score ≤ -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 ≤ -3.0 (see Note)

or

- ☐ A 10-year risk of hip fracture ≥ 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 was glucocorticosteroid therapy but patient now meets the 'Underlying cause - Osteoporosis' criteria)

and

☐ The patient will not be prescribed more than one infusion in a 12-month period

Note:

1. 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.
2. Evidence used by National Institute for Health and Clinical Excellence (NICE) guidance indicates 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 ≤ -2.5 and, therefore, do not require BMD measurement for treatment with bisphosphonates.
3. 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.
4. 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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