MEDICARE FORM

Prolia®, Xgeva® (denosumab) Injectable Medication Precertification Request

(All fields must be completed and legible for precertification review.)

For Michigan MMP:
FAX: 1-844-241-2495
PHONE: 1-855-676-5772

For other lines of business:
Please use other form.

Note: Xgeva is non-preferred. The preferred product is pamidronate or zoledronic acid. Pamidronate and zoledronic acid do not require precertification.

Please indicate: ☐ Start of treatment: Start date: ____/____/____ ☐ Continuation of therapy: Date of last treatment ____/____/____

Precertification Requested By: _____ Phone: _____ Fax: _____

A. PATIENT INFORMATION

First Name:	Last Name:		DOB:	
Address:		City:	State:	ZIP:
Home Phone:	Work Phone:	Cell Phone:	Email:	
Current Weight: _____ lbs or _____ kgs	Height: _____ inches or _____ cms		Allergies:	

B. INSURANCE INFORMATION

Aetna Member ID #: _____
Group #: _____
Insured: _____

Does patient have other coverage? ☐ Yes ☐ No
If yes, provide ID#: _____ Carrier Name: _____
Insured: _____

C. PRESCRIBER INFORMATION

First Name:	Last Name:		*(Check one):* ☐ M.D. ☐ D.O. ☐ N.P. ☐ P.A.		
Address:		City:	State:	ZIP:	
Phone:	Fax:	St Lic #:	NPI #:	DEA #:	UPIN:
Office Contact Name:			Phone:		

D. DISPENSING PROVIDER/ADMINISTRATION INFORMATION

Place of Administration:
☐ Self-administered ☐ Physician's Office
☐ Outpatient Infusion Center Phone: _____
Center Name: _____
☐ Home Infusion Center Phone: _____
Agency Name: _____
☐ Administration code(s) (CPT): _____
Address: _____

Dispensing Provider/Pharmacy:
☐ Physician's Office ☐ Retail Pharmacy
☐ Specialty Pharmacy ☐ Other: _____
Name: _____
Address: _____
Phone: _____ Fax: _____
TIN: _____ NPI: _____

E. PRODUCT INFORMATION

Request is for: ☐ Prolia ☐ Xgeva **Dose:** _____ **Frequency:** _____ **HCPCS Code**: _____

F. DIAGNOSIS INFORMATION – Please indicate primary ICD code and specify any other where applicable.

Primary ICD Code: _____ Secondary ICD Code: _____ Other ICD Code: _____

G. CLINICAL INFORMATION – Required clinical information must be completed in its **entirety** for all precertification requests.

For All Requests: (Clinical documentation required for all requests)

Note: Xgeva is non-preferred. The preferred product is pamidronate or zoledronic acid. Pamidronate and zoledronic acid do not require precertification.

☐ Yes ☐ No Has the patient had prior therapy with Xgeva (denosumab) within the last 365 days?
☐ Yes ☐ No Has the patient had a trial, intolerance, or contraindication to pamidronate or zoledronic acid?
Please explain if there are any other medical reason(s) that the patient cannot use pamidronate or zoledronic acid.

_____

_____

Please provide the patient's Bone Mineral Density (BMD) score and date obtained: T-score: _____ Date: ____/____/____
Please indicate the location the BMD was measured: ☐ femoral neck ☐ lumbar spine ☐ total hip ☐ other: please identify: _____
☐ Yes ☐ No Is the patient receiving 1000mg of calcium and 400 international units of vitamin D daily?
☐ Yes ☐ No Does the patient have clinical evidence of uncorrected preexisting hypocalcemia?
☐ Yes ☐ No Will the patient be using denosumab in combination with intravenous bisphosphonates?
☐ Yes ☐ No Will the patient be using Prolia in combination with Xgeva?
☐ Yes ☐ No Is the patient at high risk for fractures?
☐ Yes ☐ No Has the patient had an osteoporotic fracture?
→ ☐ Yes ☐ No Does the patient have multiple risk factors for fractures?
Please explain (select all that apply): ☐ alcohol intake of 4 or more units per day ☐ parental history of hip fracture
☐ rheumatoid arthritis ☐ current tobacco smoking ☐ advanced age ☐ frailty ☐ increased fall risk
☐ glucocorticoid use ☐ none of the above
☐ Yes ☐ No Does the patient have a high FRAX fracture probability: 10-year major osteoporotic fracture risk ≥ 20% or hip fracture risk ≥ 3%?
☐ Yes ☐ No Is the patient pregnant or planning to become pregnant within 5 months of discontinuing treatment with denosumab?
→ Please select: ☐ pregnant ☐ planning to become pregnant ☐ not pregnant or planning to become pregnant
☐ none of the above (e.g. male, not a female of childbearing potential)

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Patient First Name	Patient Last Name	Patient Phone	Patient DOB

G. CLINICAL INFORMATION *(continued)* – Required clinical information must be completed in its entirety for all precertification requests.

For Prolia Requests:

Post-menopausal osteoporosis

Please select which of the following medication(s) was ineffective, not tolerated or contraindicated:

Select all that apply: ☐ Alendronate (Binosto, Fosamax or Fosamax plus D) ☐ Etidronate disodium (Didronel) ☐ Ibandronate (Boniva)
☐ Risedronate (Actonel, Actonel with Calcium or Atelvia) ☐ Teriparatide (Forteo, Bonsity) ☐ Zoledronic acid (Zometa, Reclast)
☐ Raloxifene (Evista) ☐ Tamoxifen (Nolvadex/Soltamox) ☐ Toremifene citrate (Fareston)
☐ Other: Please identify: _____

Prevention or treatment of osteoporosis in patients receiving endocrine therapy for breast cancer

☐ Yes ☐ No Is the patient receiving endocrine therapy for breast cancer?
→ Please indicate which of the following endocrine therapy (aromatase inhibitors) is being used:
☐ anastrozole (Arimidex) ☐ exemestane (Aromasin) ☐ letrozole (Femara) ☐ Other: please identify: _____

☐ Yes ☐ No Is there documentation that the trial of oral and/or injectable bisphosphonates was ineffective?
→ Please identify the failure of the medication trial: ☐ Continued bone loss ☐ Other: please identify: _____
Bisphosphonate #1 Date range: ____/____/____ - ____/____/____
Bisphosphonate #2 Date range: ____/____/____ - ____/____/____

☐ Yes ☐ No Is there documented evidence that the patient has an intolerance to bisphosphonates?
☐ Yes ☐ No Is there documented evidence that the patient has a contraindication to bisphosphonates?

Please select which of the following bisphosphonates was ineffective, not tolerated or contraindicated:

Select all that apply: ☐ Alendronate (Binosto, Fosamax or Fosamax plus D) ☐ Etidronate disodium (Didronel) ☐ Ibandronate (Boniva)
☐ Risedronate (Actonel, Actonel with Calcium or Atelvia) ☐ Zoledronic acid (Zometa, Reclast)
☐ Other: Please identify: _____

Treatment to increase bone mass in men receiving androgen deprivation therapy

☐ Yes ☐ No Does the patient have prostate cancer?
☐ Yes ☐ No Is the patient receiving androgen deprivation therapy?

Treatment of bone loss in men with osteoporosis

☐ Yes ☐ No Is there documentation that the patient had an oral or injectable bisphosphonate trial of at least 1-year duration?
→ Please identify the failure of the medication trial: ☐ Continued bone loss ☐ Other: please identify: _____
Bisphosphonate #1 Date range: ____/____/____ - ____/____/____
Bisphosphonate #2 Date range: ____/____/____ - ____/____/____

☐ Yes ☐ No Is there documented evidence that the patient has an intolerance to bisphosphonates?
☐ Yes ☐ No Is there documented evidence that the patient has a contraindication to bisphosphonates?

Please select which of the following bisphosphonates was ineffective, not tolerated or contraindicated:

Select all that apply: ☐ Alendronate (Binosto, Fosamax or Fosamax plus D) ☐ Etidronate disodium (Didronel) ☐ Ibandronate (Boniva)
☐ Risedronate (Actonel, Actonel with Calcium or Atelvia) ☐ Zoledronic acid (Zometa, Reclast)
☐ Other: Please identify: _____

Treatment of glucocorticoid-induced osteoporosis

☐ Yes ☐ No Is the patient initiating or continuing systemic glucocorticoids at a daily dosage equivalent to 2.5 mg or greater of prednisone for 3 months or more?
→ Please select: ☐ initiating systemic glucocorticoids ☐ continuing systemic glucocorticoids
☐ Yes ☐ No Is the patient expected to remain on glucocorticoids for at least 6 months?

☐ Yes ☐ No Is there documentation that the trial of oral and/or injectable bisphosphonates was ineffective?
→ Please identify the failure of the medication trial: ☐ Continued bone loss ☐ Other: please identify: _____
Bisphosphonate #1 Date range: ____/____/____ - ____/____/____
Bisphosphonate #2 Date range: ____/____/____ - ____/____/____

☐ Yes ☐ No Is there documented evidence that the patient has an intolerance to bisphosphonates?
☐ Yes ☐ No Is there documented evidence that the patient has a contraindication to bisphosphonates?

Please select which of the following bisphosphonates was ineffective, not tolerated or contraindicated:

Select all that apply: ☐ Alendronate (Binosto, Fosamax or Fosamax plus D) ☐ Etidronate disodium (Didronel) ☐ Ibandronate (Boniva)
☐ Risedronate (Actonel, Actonel with Calcium or Atelvia) ☐ Zoledronic acid (Zometa, Reclast)
☐ Other: Please identify: _____

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G. CLINICAL INFORMATION (*continued*) - Required clinical information must be completed for ALL precertification requests.

For Xgeva Requests:

Bone metastases from solid tumors

Please indicate which of the following pertains to the patient: ☐ Bladder cancer ☐ Breast cancer ☐ Kidney cancer ☐ Ovarian cancer ☐ Non-small cell lung cancer ☐ Prostate cancer ☐ Thyroid cancer ☐ Other: Please specify: _____

☐ **Giant cell tumor of the bone**

☐ **Prevention of skeletal-related events in patients with multiple myeloma**

Treatment of hypercalcemia of malignancy

☐ Yes ☐ No Has the patient been treated with intravenous bisphosphonate therapy?
→ Please indicate the date range of therapy: ____/____/____ - ____/____/____

☐ Yes ☐ No Is the hypercalcemia of malignancy refractory to intravenous bisphosphonate therapy?

☐ Yes ☐ No Has the albumin-corrected serum calcium level been tested?
→ Please provide the albumin-corrected serum calcium level: _____mg/dL Date: ____/____/____

For Continuation Requests: (Clinical documentation required for all requests)

☐ Yes ☐ No Does the patient have a hypersensitivity to denosumab?

Please indicate what type of response the patient has experienced while on denosumab: ☐ No response ☐ Minimal response ☐ Adequate response ☐ Significant improvement

H. ACKNOWLEDGEMENT

Request Completed By *(Signature Required):* _____ **Date:** ____/____/____

Any person who knowingly files a request for authorization of coverage of a medical procedure or service with the intent to injure, defraud or deceive any insurance company by providing materially false information or conceals material information for the purpose of misleading, commits a fraudulent insurance act, which is a crime and subjects such person to criminal and civil penalties.

The plan may request additional information or clarification, if needed, to evaluate requests.