Drug Name: Prolia (denosumab)

Date: 9-2017
Last Revision date: 5-2019
Scope: Medicaid & Exchange

Drug Name:	Prolia (denosumab)
Required Medical Information:	• **Osteoporosis in Postmenopausal Women** Authorization of 12 months may be granted to postmenopausal female members when ANY of the following criteria are met: o Member has a history of fragility fractures o Member has a pre-treatment T-score of < -2.5 OR member has osteopenia with a high pre-treatment FRAX fracture probability (See Appendix B) and meets ANY of the following criteria: ▪ Member has indicators of higher fracture risk (e.g., advanced age, frailty, glucocorticoid use, very low T-scores, or increased fall risk) ▪ Member has failed prior treatment with or is intolerant to previous injectable osteoporosis therapy (e.g., zoledronic acid [Reclast], teriparatide [Forteo]) ▪ Member has had an oral bisphosphonate trial of at least 1-year duration or there is a clinical reason to avoid treatment with an oral bisphosphonate (See Appendix A) • **Osteoporosis in Men** Authorization of 12 months may be granted to male members with osteoporosis when ANY of the following criteria are met: o Member has a history of an osteoporotic vertebral or hip fracture o Member has a pre-treatment T-score of < -2.5 o Member has osteopenia with a high pre-treatment FRAX fracture probability (See Appendix B) • **Breast Cancer** Authorization of 12 months may be granted to members who are receiving adjuvant aromatase inhibitor therapy for breast cancer. • **Prostate Cancer** Authorization of 12 months may be granted to members who are receiving androgen deprivation therapy for prostate cancer.

	• **Glucocorticoid-induced Osteoporosis** Authorization of 12 months may be granted to members with glucocorticoid-induced osteoporosis when ALL of the following criteria are met: o Member is currently receiving or will be initiating glucocorticoid therapy o Member has had an oral bisphosphonate trial of at least 1-year duration OR there is a clinical reason to avoid treatment with an oral bisphosphonate (See Appendix A) o Member meets ANY of the following criteria: ▪ Member has a history of a fragility fracture ▪ Member has a pre-treatment T-score of ≤ -2.5 ▪ Member has osteopenia with a high pre-treatment FRAX fracture probability (See Appendix B)
Renewal Critiera:	All members (including new members) requesting authorization for continuation of therapy must meet all initial authorization criteria.
Appendix:	Appendix A. <u>Clinical reasons to avoid oral bisphosphonate therapy</u> • Esophageal abnormality that delays emptying such as stricture of achalasia • Active upper gastrointestinal problem (e.g., dysphagia, gastritis, duodenitis, erosive esophagitis, ulcers) • Inability to stand or sit upright for at least 30 to 60 minutes • Inability to take at least 30 to 60 minutes before first food, drink, or medication of the day • Renal insufficiency (creatinine clearance < 35mL/min) • History of intolerance to an oral bisphosphonate Appendix B. <u>WHO Fracture Risk Assessment Tool</u> • High FRAX fracture probability: 10 year major osteoporotic fracture risk ≥ 20% or hip fracture risk ≥ 3%. • 10-year probability; calculation tool available at: http://www.shef.ac.uk/FRAX/tool.jsp

Drug Name: Prolia (denosumab)

Date: 9-2017
Last Revision date: 5-2019
Scope: Integrity

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Required Medical Information:	• **Osteoporosis in Postmenopausal Women** Authorization of 12 months may be granted to postmenopausal female members when ANY of the following criteria are met: o Member has a history of fragility fractures o Member has a pre-treatment T-score of < -2.5 OR member has osteopenia with a high pre-treatment FRAX fracture probability (See Appendix B) and meets ANY of the following criteria: ▪ Member has indicators of higher fracture risk (e.g., advanced age, frailty, glucocorticoid use, very low T-scores, or increased fall risk) ▪ Member has failed prior treatment with or is intolerant to previous injectable osteoporosis therapy (e.g., zoledronic acid [Reclast], teriparatide [Forteo]) OR oral bisphosphonate trial of at least 1-year duration or there is a clinical reason to avoid treatment with an oral bisphosphonate (See Appendix A) • **Osteoporosis in Men** Authorization of 12 months may be granted to male members with osteoporosis when ANY of the following criteria are met: o Member has a history of an osteoporotic vertebral or hip fracture o Member has a pre-treatment T-score of < -2.5 o Member has osteopenia with a high pre-treatment FRAX fracture probability (See Appendix B) • **Breast Cancer** Authorization of 12 months may be granted to members who are receiving adjuvant aromatase inhibitor therapy for breast cancer. • **Prostate Cancer** Authorization of 12 months may be granted to members who are receiving androgen deprivation therapy for prostate cancer.

	• **Glucocorticoid-induced Osteoporosis** Authorization of 12 months may be granted to members with glucocorticoid-induced osteoporosis when ALL of the following criteria are met: o Member is currently receiving or will be initiating glucocorticoid therapy o Member has had an oral bisphosphonate trial of at least 1-year duration OR there is a clinical reason to avoid treatment with an oral bisphosphonate (See Appendix A) o Member meets ANY of the following criteria: ▪ Member has a history of a fragility fracture ▪ Member has a pre-treatment T-score of ≤ -2.5 ▪ Member has osteopenia with a high pre-treatment FRAX fracture probability (See Appendix B)
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