 Draft Revision Policy: Do Not Implement

Denosumab Products: Denosumab (Xgeva®); Denosumab-kyqq (Aukelso™); Denosumab-nxxp (Bilprevda®); Denosumab-bnht (Bomyntra®); Denosumab-bmwo (Osenvelt®); Denosumab-bbdz (Wyost®); Denosumab-dssb (Xbryk™), Denosumab-qbde (Xtrenbo™)

IMPORTANT REMINDER

We develop Medical Policies to provide guidance to Members and Providers. This Medical Policy relates only to the services or supplies described in it. The existence of a Medical Policy is not an authorization, certification, explanation of benefits or a contract for the service (or supply) that is referenced in the Medical Policy. For a determination of the benefits that a Member is entitled to receive under his or her health plan, the Member's health plan must be reviewed. If there is a conflict between the medical policy and a health plan or government program (e.g., TennCare), the express terms of the health plan or government program will govern.

The proposal is to add text/statements in red and to delete text/statements with strikethrough:

POLICY

INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications

- Prevention of skeletal-related events in patients with multiple myeloma and in patients with bone metastases from solid tumors
- Treatment of adults and skeletally mature adolescents with giant cell tumor of bone that is unresectable or where surgical resection is likely to result in severe morbidity
- Treatment of hypercalcemia of malignancy refractory to bisphosphonate therapy

Compendial Uses

- Second-line therapy for osteopenia/osteoporosis in patients with systemic mastocytosis
- Thyroid cancer as palliative care for bone metastases

All other indications are considered experimental/investigational and not medically necessary.

COVERAGE CRITERIA

Multiple Myeloma

Authorization of 12 months may be granted for prevention of skeletal-related events in members with multiple myeloma.

Bone Metastases From a Solid Tumor

Authorization of 12 months may be granted for either of the following:

- For prevention of skeletal-related events in members with bone metastases from a solid tumor (e.g., breast cancer, non-small cell lung cancer, thyroid carcinoma, kidney cancer, prostate cancer)
- As palliative care for bone metastases from thyroid carcinoma

Giant Cell Tumor of Bone

Authorization of 12 months may be granted for treatment of giant cell tumor of bone.

Hypercalcemia of Malignancy

Authorization of 2 months may be granted for treatment of hypercalcemia of malignancy that is refractory to intravenous (IV) bisphosphonate therapy OR there is a clinical reason to avoid IV bisphosphonate therapy (see Appendix).

Systemic Mastocytosis

Authorization of 12 months may be granted for second-line therapy for osteopenia or osteoporosis in members with systemic mastocytosis that have not responded to therapy with bisphosphonates or who are not candidates for bisphosphonates because of renal insufficiency.

CONTINUATION OF THERAPY

Hypercalcemia of Malignancy

Authorization of 2 months may be granted for continued treatment in members requesting reauthorization for hypercalcemia of malignancy who are experiencing benefit from therapy as evidenced by disease stability or disease improvement.

All Other Indications

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in the coverage criteria who are experiencing benefit from therapy as evidenced by disease stability or disease improvement.

MEDICATION QUANTITY LIMITS

Drug Name	Diagnosis	Maximum Dosing Regimen
Xgeva (Denosumab)	Giant Cell Tumor of the Bone	Route of Administration: Subcutaneous 120mg on days 1, 8, and 15 of the first month of therapy, followed by 120 mg every 4 weeks
Xgeva (Denosumab)	Hypercalcemia of Malignancy	Route of Administration: Subcutaneous 120mg on days 1, 8, and 15 of the first month of therapy, followed by 120 mg every 4 weeks
Xgeva (Denosumab)	Osteopenia or Osteoporosis in patients with Systemic Mastocytosis	Route of Administration: Subcutaneous 60mg every 6 months
Xgeva (Denosumab)	Palliative Care for Bone Metastases from Thyroid Carcinoma	Route of Administration: Subcutaneous 120mg every 4 weeks
Xgeva (Denosumab)	Prevention of Skeletal-Related Events in Patients with Bone Metastases from Solid Tumors	Route of Administration: Subcutaneous 120mg every 4 weeks

Xgeva (Denosumab)	Prevention of Skeletal-Related Events in Patients with Multiple Myeloma	Route of Administration: Subcutaneous 120mg every 4 weeks
Aukelso (Denosumab-kyqq)	Giant Cell Tumor of the Bone	Route of Administration: Subcutaneous 120mg on days 1, 8, and 15 of the first month of therapy, followed by 120 mg every 4 weeks
Aukelso (Denosumab-kyqq)	Hypercalcemia of Malignancy	Route of Administration: Subcutaneous 120mg on days 1, 8, and 15 of the first month of therapy, followed by 120 mg every 4 weeks
Aukelso (Denosumab-kyqq)	Osteopenia or Osteoporosis in patients with Systemic Mastocytosis	Route of Administration: Subcutaneous 60mg every 6 months
Aukelso (Denosumab-kyqq)	Palliative Care for Bone Metastases from Thyroid Carcinoma	Route of Administration: Subcutaneous 120mg every 4 weeks
Aukelso (Denosumab-kyqq)	Prevention of Skeletal-Related Events in Patients with Bone Metastases from Solid Tumors	Route of Administration: Subcutaneous 120mg every 4 weeks
Aukelso (Denosumab-kyqq)	Prevention of Skeletal-Related Events in Patients with Multiple Myeloma	Route of Administration: Subcutaneous 120mg every 4 weeks
Bilprevda (Denosumab-nxxp)	Giant Cell Tumor of the Bone	Route of Administration: Subcutaneous 120mg on days 1, 8, and 15 of the first month of therapy, followed by 120 mg every 4 weeks
Bilprevda (Denosumab-nxxp)	Hypercalcemia of Malignancy	Route of Administration: Subcutaneous 120mg on days 1, 8, and 15 of the first month of therapy, followed by 120 mg every 4 weeks
Bilprevda (Denosumab-nxxp)	Osteopenia or Osteoporosis in patients with Systemic Mastocytosis	Route of Administration: Subcutaneous 60mg every 6 months
Bilprevda (Denosumab-nxxp)	Palliative Care for Bone Metastases from Thyroid Carcinoma	Route of Administration: Subcutaneous 120mg every 4 weeks
Bilprevda (Denosumab-nxxp)	Prevention of Skeletal-Related Events in Patients with Bone Metastases from Solid Tumors	Route of Administration: Subcutaneous 120mg every 4 weeks
Bilprevda (Denosumab-nxxp)	Prevention of Skeletal-Related Events in Patients with Multiple Myeloma	Route of Administration: Subcutaneous 120mg every 4 weeks
Bomyntra (Denosumab-bnht)	Giant Cell Tumor of the Bone	Route of Administration: Subcutaneous 120mg on days 1, 8, and 15 of the first month of therapy, followed by 120 mg every 4 weeks
Bomyntra (Denosumab-bnht)	Hypercalcemia of Malignancy	Route of Administration: Subcutaneous 120mg on days 1, 8, and 15 of the first month of therapy, followed by 120 mg every 4 weeks
Bomyntra (Denosumab-bnht)	Osteopenia or Osteoporosis in patients with Systemic Mastocytosis	Route of Administration: Subcutaneous 60mg every 6 months

Bomyntra (Denosumab-bnht)	Palliative Care for Bone Metastases from Thyroid Carcinoma	Route of Administration: Subcutaneous 120mg every 4 weeks
Bomyntra (Denosumab-bnht)	Prevention of Skeletal-Related Events in Patients with Bone Metastases from Solid Tumors	Route of Administration: Subcutaneous 120mg every 4 weeks
Bomyntra (Denosumab-bnht)	Prevention of Skeletal-Related Events in Patients with Multiple Myeloma	Route of Administration: Subcutaneous 120mg every 4 weeks
Osenvelt (Denosumab-bmwo)	Giant Cell Tumor of the Bone	Route of Administration: Subcutaneous 120mg on days 1, 8, and 15 of the first month of therapy, followed by 120 mg every 4 weeks
Osenvelt (Denosumab-bmwo)	Hypercalcemia of Malignancy	Route of Administration: Subcutaneous 120mg on days 1, 8, and 15 of the first month of therapy, followed by 120 mg every 4 weeks
Osenvelt (Denosumab-bmwo)	Osteopenia or Osteoporosis in patients with Systemic Mastocytosis	Route of Administration: Subcutaneous 60mg every 6 months
Osenvelt (Denosumab-bmwo)	Palliative Care for Bone Metastases from Thyroid Carcinoma	Route of Administration: Subcutaneous 120mg every 4 weeks
Osenvelt (Denosumab-bmwo)	Prevention of Skeletal-Related Events in Patients with Bone Metastases from Solid Tumors	Route of Administration: Subcutaneous 120mg every 4 weeks
Osenvelt (Denosumab-bmwo)	Prevention of Skeletal-Related Events in Patients with Multiple Myeloma	Route of Administration: Subcutaneous 120mg every 4 weeks
Wyost (Denosumab-bbdz)	Giant Cell Tumor of the Bone	Route of Administration: Subcutaneous 120mg on days 1, 8, and 15 of the first month of therapy, followed by 120 mg every 4 weeks
Wyost (Denosumab-bbdz)	Hypercalcemia of Malignancy	Route of Administration: Subcutaneous 120mg on days 1, 8, and 15 of the first month of therapy, followed by 120 mg every 4 weeks
Wyost (Denosumab-bbdz)	Osteopenia or Osteoporosis in patients with Systemic Mastocytosis	Route of Administration: Subcutaneous 60mg every 6 months
Wyost (Denosumab-bbdz)	Palliative Care for Bone Metastases from Thyroid Carcinoma	Route of Administration: Subcutaneous 120mg every 4 weeks
Wyost (Denosumab-bbdz)	Prevention of Skeletal-Related Events in Patients with Bone Metastases from Solid Tumors	Route of Administration: Subcutaneous 120mg every 4 weeks
Wyost (Denosumab-bbdz)	Prevention of Skeletal-Related Events in Patients with Multiple Myeloma	Route of Administration: Subcutaneous 120mg every 4 weeks

Xbryk (Denosumab-dssb)	Giant Cell Tumor of the Bone	Route of Administration: Subcutaneous 120mg on days 1, 8, and 15 of the first month of therapy, followed by 120 mg every 4 weeks
Xbryk (Denosumab-dssb)	Hypercalcemia of Malignancy	Route of Administration: Subcutaneous 120mg on days 1, 8, and 15 of the first month of therapy, followed by 120 mg every 4 weeks
Xbryk (Denosumab-dssb)	Osteopenia or Osteoporosis in patients with Systemic Mastocytosis	Route of Administration: Subcutaneous 60mg every 6 months
Xbryk (Denosumab-dssb)	Palliative Care for Bone Metastases from Thyroid Carcinoma	Route of Administration: Subcutaneous 120mg every 4 weeks
Xbryk (Denosumab-dssb)	Prevention of Skeletal-Related Events in Patients with Bone Metastases from Solid Tumors	Route of Administration: Subcutaneous 120mg every 4 weeks
Xbryk (Denosumab-dssb)	Prevention of Skeletal-Related Events in Patients with Multiple Myeloma	Route of Administration: Subcutaneous 120mg every 4 weeks

~~Drug Name~~	~~Diagnosis~~	~~Maximum Dosing Regimen~~
~~Xgeva (Denosumab)~~ ~~Bomyntra (Denosumab-bnht)~~ ~~Osenvelt (Denosumab-bmwo)~~ ~~Wyost (Denosumab-bbdz)~~ ~~Xbryk (Denosumab-dssb)~~	~~Giant Cell Tumor of the Bone~~	~~Route of Administration: Subcutaneous~~ ~~120mg on days 1, 8, and 15 of the first month of therapy, followed by 120 mg every 4 weeks~~
~~Xgeva (Denosumab)~~ ~~Bomyntra (Denosumab-bnht)~~ ~~Osenvelt (Denosumab-bmwo)~~ ~~Wyost (Denosumab-bbdz)~~ ~~Xbryk (Denosumab-dssb)~~	~~Hypercalcemia of Malignancy~~	~~Route of Administration: Subcutaneous~~ ~~120mg on days 1, 8, and 15 of the first month of therapy, followed by 120 mg every 4 weeks~~
~~Xgeva (Denosumab)~~ ~~Bomyntra (Denosumab-bnht)~~ ~~Osenvelt (Denosumab-bmwo)~~ ~~Wyost (Denosumab-bbdz)~~ ~~Xbryk (Denosumab-dssb)~~	~~Osteopenia or Osteoporosis in patients with Systemic Mastocytosis~~	~~Route of Administration: Subcutaneous~~ ~~60mg every 6 months~~

~~Xgeva (Denosumab)~~ ~~Bomyntra (Denosumab-bnht)~~ ~~Osenvelt (Denosumab-bmwo)~~ ~~Wyost (Denosumab-bbdz)~~ ~~Xbryk (Denosumab-dssb)~~	~~Palliative Care for Bone Metastases from Thyroid Carcinoma~~	~~Route of Administration: Subcutaneous 120mg every 4 weeks~~
~~Xgeva (Denosumab)~~ ~~Bomyntra (Denosumab-bnht)~~ ~~Osenvelt (Denosumab-bmwo)~~ ~~Wyost (Denosumab-bbdz)~~ ~~Xbryk (Denosumab-dssb)~~	~~Prevention of Skeletal-Related Events in Patients with Bone Metastases from Solid Tumors~~	~~Route of Administration: Subcutaneous 120mg every 4 weeks~~
~~Xgeva (Denosumab)~~ ~~Bomyntra (Denosumab-bnht)~~ ~~Osenvelt (Denosumab-bmwo)~~ ~~Wyost (Denosumab-bbdz)~~ ~~Xbryk (Denosumab-dssb)~~	~~Prevention of Skeletal-Related Events in Patients with Multiple Myeloma~~	~~Route of Administration: Subcutaneous 120mg every 4 weeks~~

APPENDIX

Appendix: Clinical Reasons to Avoid IV Bisphosphonate Therapy

- Renal insufficiency (creatinine clearance < 35 mL/min)
- Acute renal impairment
- History of intolerance to an IV bisphosphonate

APPLICABLE TENNESSEE STATE MANDATE REQUIREMENTS

BlueCross BlueShield of Tennessee's Medical Policy complies with Tennessee Code Annotated Section 56-7-2352 regarding coverage of off-label indications of Food and Drug Administration (FDA) approved drugs when the off-label use is recognized in one of the statutorily recognized standard reference compendia or in the published peer-reviewed medical literature.

ADDITIONAL INFORMATION

For appropriate chemotherapy regimens, dosage information, contraindications, precautions, warnings, and monitoring information, please refer to one of the standard reference compendia (e.g., the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) published by the National Comprehensive Cancer Network®, Drugdex Evaluations of Micromedex Solutions at Truven Health, or The American Hospital Formulary Service Drug Information).

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EFFECTIVE DATE

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