Initiating XGEVA®:

Quick-start guide for healthcare professionals

XGEVA (denosumab) is indicated for reducing the risk of developing skeletal-related events (SREs) in patients with multiple myeloma and in patients with bone metastases from breast cancer, prostate cancer, non-small cell lung cancer and other solid tumours.

PREPARING FOR XGEVA

- ❑ Ask patients if they have **private insurance** coverage and refer them to the **VICTORY® program** for assistance with accessing XGEVA as well as ongoing patient support.
  - › Patients can enrol by calling a VICTORY® Access Specialist at 1-888-706-4717 Monday to Friday, 8:00 a.m. to 8:00 p.m. EST, or by downloading the enrolment form at www.VictoryAssist.ca and faxing it to 1-833-884-5608.
- ❑ Perform an **oral exam** prior to treatment initiation.
  - › Appropriate preventive dentistry is also recommended, especially in patients with risk factors for osteonecrosis of the jaw (ONJ).
- ❑ Check **calcium levels** and correct pre-existing hypocalcemia if present.

STARTING XGEVA

- ❑ Administer XGEVA at a dose of **120 mg SC Q4W**.
- ❑ Discuss the importance of taking **daily calcium (≥ 500 mg) and vitamin D (≥ 400 IU)**, except in patients with hypercalcemia.
- ❑ Advise patients to maintain good **oral hygiene** practices and to avoid invasive dental procedures during treatment with XGEVA.

CONTINUING TREATMENT WITH XGEVA

- ❑ Monitor **calcium levels** as needed, including within two weeks of the first dose and at any time if suspected symptoms of hypocalcemia occur.
- ❑ Encourage patients to have **routine dental check-ups** throughout treatment with XGEVA, and to immediately report any oral symptoms such as dental mobility, pain, or swelling.
- ❑ Continue treatment with XGEVA at a dose of **120 mg SC Q4W**. Patients may self-inject XGEVA after an initial training in proper SC injection technique, with medical follow-up as necessary.

See Product Monograph for complete dosing, administration and monitoring instructions.

SC: subcutaneous
Q4W: once every 4 weeks
IU: international units

XGEVA® (denosumab)

Notes

Important safety information

Clinical use:

- XGEVA is not indicated for use in pediatric patients other than skeletally mature adolescents (aged 13–17 years) with giant cell tumour of bone.

Contraindications:

- XGEVA is contraindicated in patients with pre-existing hypocalcemia, which must be corrected prior to initiating therapy.

Most serious warnings and precautions:

Osteonecrosis of the jaw (ONJ): In clinical trials, the incidence of ONJ was higher with longer duration of exposure. In patients with risk factors for ONJ, an individual benefit-risk assessment should be performed before initiating therapy with XGEVA. An oral exam should be performed, and a dental exam with appropriate preventive dentistry is recommended prior to treatment with XGEVA, especially in patients with risk factors for ONJ. Avoid invasive dental procedures while receiving XGEVA. In patients who develop ONJ during treatment with XGEVA, a temporary interruption of treatment should be considered based on individual benefit-risk assessment until the condition resolves.

Other relevant warnings and precautions:

- Do not use concurrently with Prolia®.
- Do not use concurrently with bisphosphonates.
- Hypocalcemia has been reported (including severe symptomatic hypocalcemia and fatal cases).
- Caution on risk of hypocalcemia and accompanying increases in parathyroid hormone in patients with renal impairment.
- Clinically significant hypercalcemia has been reported in XGEVA-treated patients with giant cell tumour of bone and in patients with growing skeletons weeks to months following treatment discontinuation.
- Skin infections.
- Hypersensitivity reactions, including anaphylaxis.
- Atypical femoral fractures.
- Multiple vertebral fractures, not due to bone metastases, may occur following discontinuation of treatment with XGEVA, particularly in patients with risk factors such as osteoporosis or prior fracture.
- Pregnancy.
- Breastfeeding.

For more information:

Please consult the Product Monograph at http://www.amgen.ca/Xgeva_PM.pdf for important information relating to adverse reactions, drug interactions, and dosing information that has not been discussed here.

The Product Monograph can also be obtained by calling Amgen Medical Information at 1-866-502-6436.

Reference: XGEVA® Product Monograph. Amgen Canada. June 14, 2019.

℞ XGEVA® (denosumab)

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