Qutenza® (capsaicin) – Expanded indication

- On July 17, 2020, the FDA approved Averitas Pharma's Qutenza (capsaicin), in adults for the treatment of neuropathic pain associated with postherpetic neuralgia (PHN) and for neuropathic pain associated with diabetic peripheral neuropathy (DPN) of the feet.
    - Qutenza was previously only approved for the management of neuropathic pain associated with postherpetic neuralgia.
- The approval of Qutenza for the expanded indication was based on one 12-week, double-blind, randomized, placebo-controlled study in patients with neuropathic pain associated with DPN. Qutenza and placebo were each applied as a single, 30-minute application.
    - The percent change in average pain from baseline to week 12 was higher in the Qutenza group vs. the placebo group. The percent change in average pain from baseline to week 12 was -22% for placebo and -30% for Qutenza.
    - The least-squares mean change was -1.92 on the 11-point Numerical Pain Rating Scale (NPRS) for Qutenza, vs -1.37 for placebo, a least-squares mean difference of -0.56 (95% CI: -0.98, -0.14).
- The recommended dose of Qutenza for neuropathic pain associated with DPN is a single, 30-minute application on the feet of up to four patches (each patch contains 8% capsaicin). Treatment with Qutenza may be repeated every three months or as warranted by the return of pain (not more frequently than every three months).
    - Only physicians or health care professionals under the close supervision of a physician are to administer Qutenza. Qutenza should not be dispensed to patients for self-administration or handling.
    - Refer to the Qutenza drug label for dosing in PHN and additional administration recommendations.