Exparel® (bupivacaine) – New indication

- On April 6, 2018, Pacira announced the FDA approval of Exparel (bupivacaine liposome injectable suspension) as an interscalene brachial plexus nerve block to produce postsurgical regional analgesia.
    - Limitations of Use: safety and efficacy have not been evaluated in other nerve blocks.
- Exparel is also approved for single-dose infiltration in adults to produce postsurgical local analgesia.
- Interscalene brachial plexus nerve blocks are injections to the nerves of the brachial plexus used to provide anesthesia and postsurgical analgesia following surgery to the clavicle, shoulder, and/or arm.
- The efficacy of Exparel in interscalene brachial plexus nerve block was based on a placebo-controlled study of 156 patients undergoing primary unilateral total shoulder arthroplasty or rotator cuff repair with general anesthesia. Patients were allowed opioid rescue medications.
    - There was a statistically significant treatment effect for Exparel compared to placebo in cumulative pain scores through 48 hours as measured by the area under the curve of the visual analog scale pain intensity scores ($p < 0.0001$).
    - There were statistically significant, but small differences in the amount of opioid consumption through 48 hours, the clinical benefit of which has not been demonstrated.
- Exparel may be dosed up to a maximum of 266 mg (20 mL) for local infiltration and 133 mg (10 mL) for interscalene brachial plexus nerve block.
    - Exparel is intended for single-dose administration only.
    - Different formulations of bupivacaine are not bioequivalent even if the milligram strength is the same. It is not possible to convert dosing from other formulations of bupivacaine to Exparel.