Dextenza® (dexamethasone ophthalmic insert) – Expanded indication

- On April 7, 2025, the FDA approved Ocular Therapeutix's Dextenza (dexamethasone ophthalmic insert), for the treatment of:
    - Ocular inflammation and pain following ophthalmic surgery in adults and pediatric patients
    - Ocular itching associated with allergic conjunctivitis in adults and pediatric patients aged 2 years and older.
- This approval expands Dextenza's indications to include pediatric patients.
- The use of Dextenza for the expanded indications is supported by evidence from adequate and well-controlled studies in adults with additional safety data from a single active-controlled study in pediatric patients aged birth to 5 years old. **A similar safety profile was observed between pediatric and adult patients**.
- Dextenza is an ophthalmic insert that is inserted in the lower lacrimal punctum into the canaliculus. A single Dextenza insert releases a 0.4 mg dose of dexamethasone for up to 30 days following insertion.
    - Dextenza is resorbable and does not require removal. Saline irrigation or manual expression can be performed to remove the insert if necessary. Dextenza is intended for single-use only.