EYEPOINT PHARMACEUTICALS

Ensuring Medicare Beneficiary Access to Innovative Ophthalmic Products for Patients with Serious Eye Disorders

Presentation to the Advisory Panel on Hospital Outpatient Payment (HOP Panel)

August 19 20, 2019

Conflict of Interest Statement

Presenter:

Dario Paggiarino, M.D., Chief Medical Officer, EyePoint Pharmaceuticals Inc.

I am an employee of EyePoint Pharmaceuticals and hold stock and stock options in the company. I have no other conflicts of interest to disclose.

EYEPOINT PHARMACEUTICALS

Request

The HOP Panel should recommend that CMS modify its current packaging policy so that FDA-approved drugs administered at the time of cataract surgery with indications to treat or prevent post-operative issues (thus replacing some or all of the post-operative eye drops that patients are prescribed for use at home and that are paid under Medicare Part D) are paid separately under Medicare Part B in the Ambulatory Surgical Center (ASC) setting.

EyePoint also endorses the request submitted by the American Society of Cataract and Refractive Surgery (ASCRS) and the Ophthalmic Pharmaceutical Coalition.

EYEPOINT PHARMACEUTICALS

Background on DEXYCU™

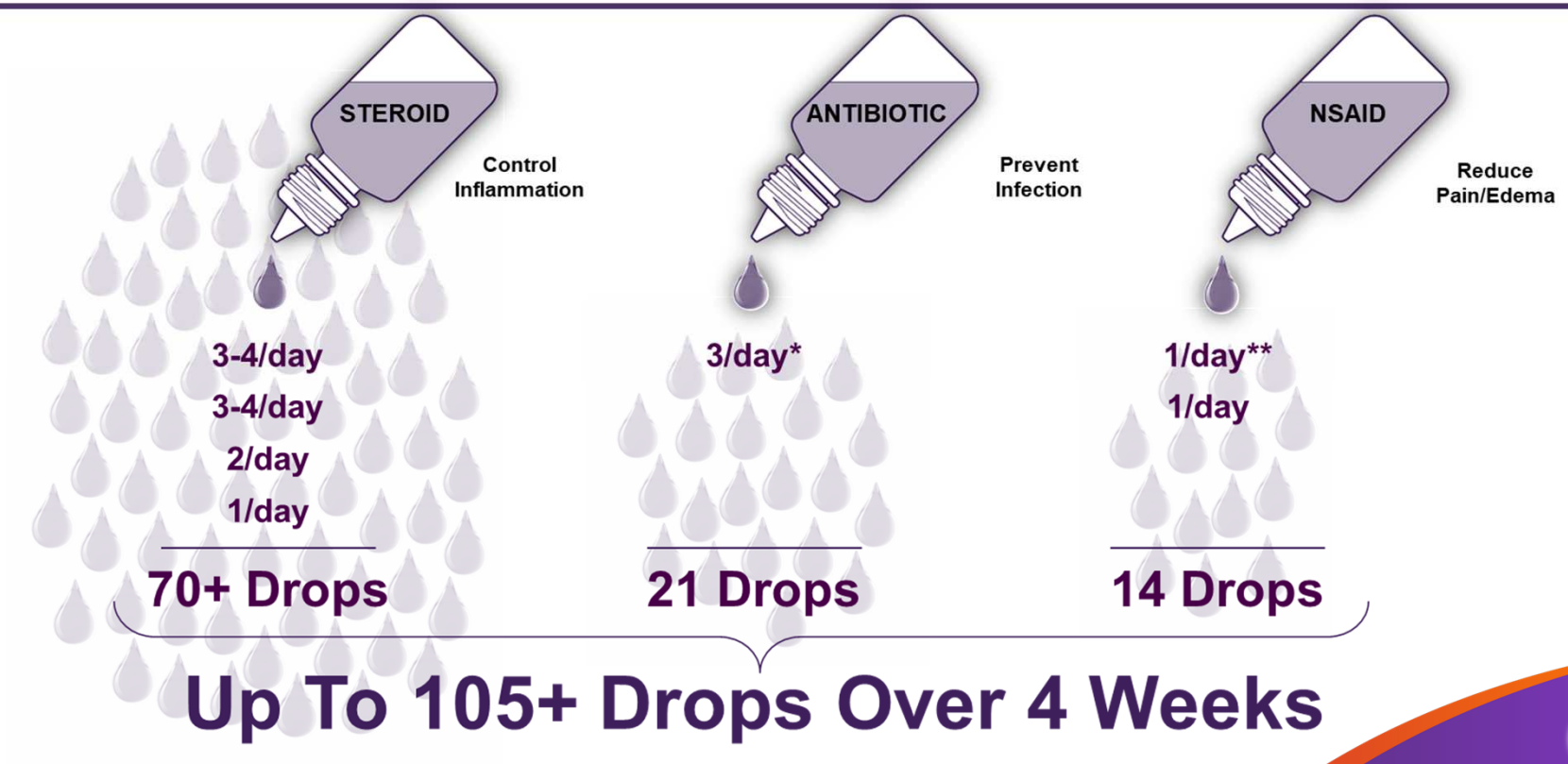
DEXYCU™
(dexamethasone intraocular suspension) 9%

Post-Cataract Surgery Inflammation

- Food and Drug Administration (FDA) approved on 2/9/18
- Drug pass-through status granted effective 10/1/18
- First Medicare claim submitted the week of 4/15/19
- Single injection at the end of eye surgery; rapidly reduces inflammation and maintains results through Day 30

EyePoint Pharmaceuticals

Current Post-Cataract Therapy Requires Polypharmacy and Places Significant Burden on Patients



*Source: Vigamox/Besivance product labeling (not specifically indicated for this use, but are commonly prescribed for use)
**Source: Prolenza/Bromday product labeling (not specifically indicated for this use, but are commonly prescribed for use)

EyePoint Pharmaceuticals

New Analysis of Cataract Surgery and Pharmacy Claims

- EyePoint commissioned a detailed data analysis from IQVIA (formerly IMS/Quintiles) – results finalized **July 2019**
  - Extensive claims analysis experience, proprietary claims data sets
  - Reviewed 443,000 claims over 4+ years (inpatient, outpatient, and pharmacy)
- IQVIA examined these data searching for trends in:
  - No fill or abandonment of eye drop prescriptions
  - Complications after surgery
  - Repeat cataract surgeries
  - Time between surgery and prescription fills
  - Use of opioid medications

EYEPOINT PHARMACEUTICALS

Data Confirm Need for Better Post-Surgical Treatment

- Lower than anticipated use of anti-inflammatory eyedrops
  - **62% of cataract patients** filled a topical steroid and/or NSAID before and/or after initial surgery vs. expected 80-85%
  - Patients are **not filling prescriptions** and/or **using workarounds** like unapproved drugs (including compounded drugs) or samples
- **19% of cataracts patients abandon** at least one of their prescription drops after filling
  - Tens of thousands of patients not getting standard of care treatment for pain and inflammation

EyePoint Pharmaceuticals

Data Confirm Need for Better Post-Surgical Treatment

- Unexpectedly high Rx rate for **opioids** after cataract surgery (20,000/year)
  - 77% of these also received an NSAID and/or steroid pre or post surgery – topical treatments did not address post-surgical pain and **patients resorted to opioids**
  - 20,000 is for ophthalmologists alone, who rarely prescribe opioids (so we know opioid relates to the surgery); 13.5% of all cataract surgery patients filled a prescription for an opioid
- Higher rates of **comorbidities** for patients who filled at least one prescription for steroid or NSAID drops vs. those who did not fill
  - Suggests patients are filling prescriptions for drops **only when needed to treat complications**

EyePoint Pharmaceuticals

Even When Patients Fill Eye Drops, Problems Abound

- Patients miss doses of the prescriptions they do fill
  - Inadequate treatment of symptoms
  - Potential contribution to antibiotic resistance
- 93% of patients improperly administer drops following cataract surgery*
  - Miss the eye
  - Incorrect number of drops
  - Contaminated bottle tip or hands
- Many patients think they use drops properly but were observed making mistakes

* Angela J, et al. Evaluation of eye drop administration by inexperienced patients after cataract surgery. Journal of Cataract and Refractive Surgery. 2014; 11. 1857-1861.

Potentially Severe Clinical Consequences from Missed Fills, Missed Doses, or Improper Administration

- Untreated inflammation, swelling, or infection > higher risk of complications
  - Complications can cause pain, visual impairment, repeat surgeries or other avoidable treatments > increased costs for federal programs and other payers
- Opioid prescriptions for patients who have post-surgical pain because of missed fills or other problems with current therapies
- Missed fills or missed doses of antibiotics may contribute to antibiotic resistance

* Schmier JK, Halpern MT, Covert DW, Matthews GP. Evaluation of costs for cystoid macular edema among patients after cataract surgery. Retina 2007; 27:621–628 (analysis of 139,759 beneficiaries with cataract surgery in the Medicare 5% Beneficiary Encrypted Files 1997 through 2001).

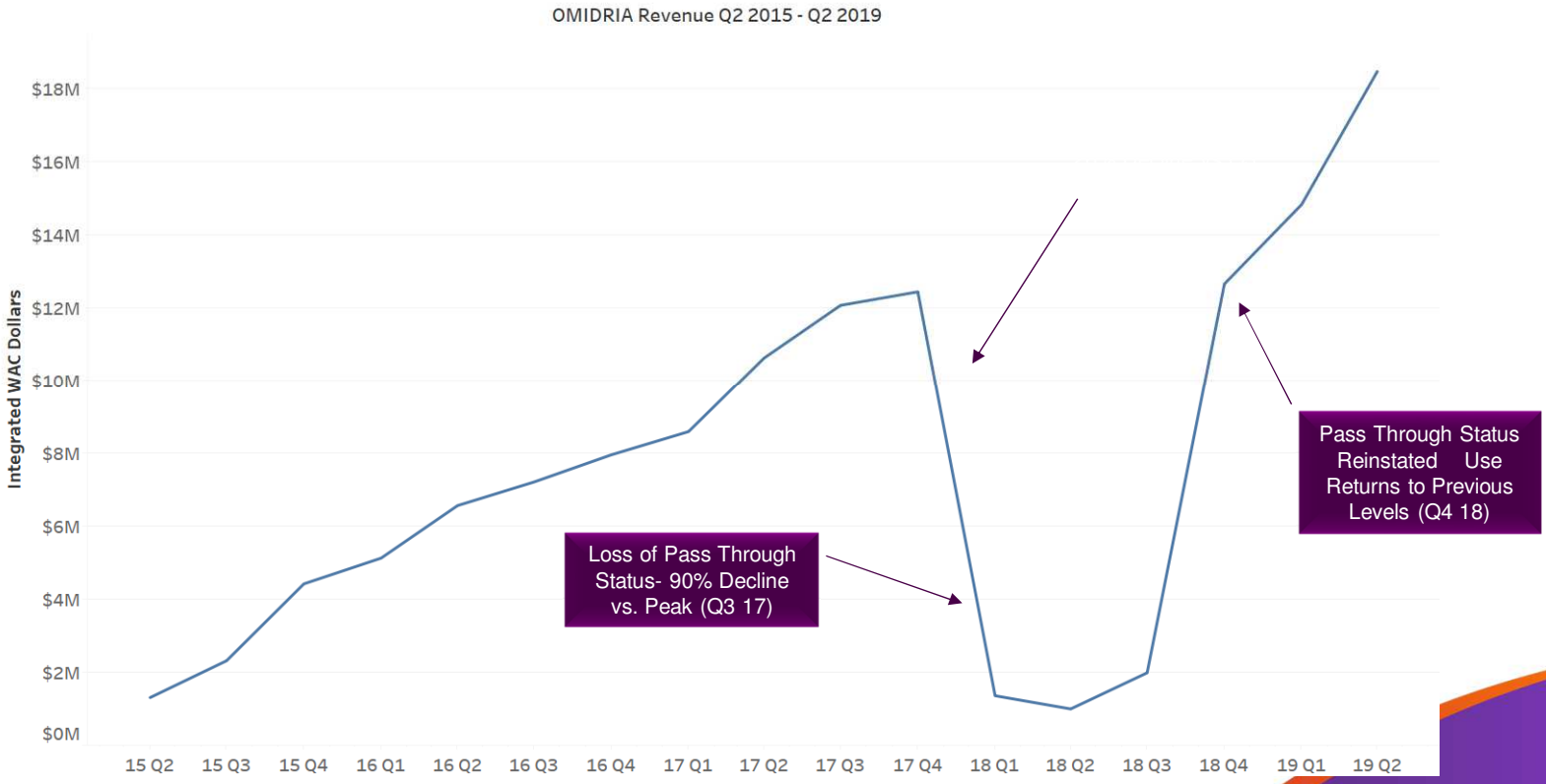
EYEPOINT PHARMACEUTICALS

Better Alternatives Are Available But CMS Policy Hinders Medicare Beneficiary Access

- Innovative ophthalmic drugs like DEXYCU™ finally offer an alternative to all the problems of eye drops
  - Single injection after surgery guarantees compliance with regimen
  - Optimal visual outcomes post-surgery
- But OPPS/ASC packaging policy **hinders patient access** to these innovative ophthalmic drugs
- CMS policy also discourages investment and development of the next innovative ophthalmic drug – no path to adequate reimbursement
- CMS should remove the barriers to patient access by paying separately for drugs that could replace some or all of the postoperative eye drops

EyePoint Pharmaceuticals

Pass-Through Status Is Not Sufficient to Ensure Medicare Beneficiary Access After It Expires



Source(s): OMEROS Public Filing Information Annually and Quarterly
Symphony Data on OMIDRIA Sales 2017 & Q1 2018

EYEPOINT PHARMACEUTICALS

Conclusion

The HOP Panel should recommend that CMS modify its current packaging policy so that FDA-approved drugs administered at the time of cataract surgery with indications to treat or prevent post-operative issues (thus replacing some or all of the post-operative eye drops that patients are prescribed for use at home and that are paid under Medicare Part D) are paid separately under Medicare Part B in the Ambulatory Surgical Center (ASC) setting.

Permanent, separate payment will help ensure that patients continue to benefit from an innovative treatment option that promotes adherence to treatment, reduces painful and costly complications, and likely reduces opioid use.

EYEPOINT PHARMACEUTICALS

Thank you!

EyePoint Pharmaceuticals