



Pediatric Utilization Patterns of Single-Ingredient Oxycodone (Extended-Release and Immediate-Release), 2013-2018

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Pediatric Advisory Committee**

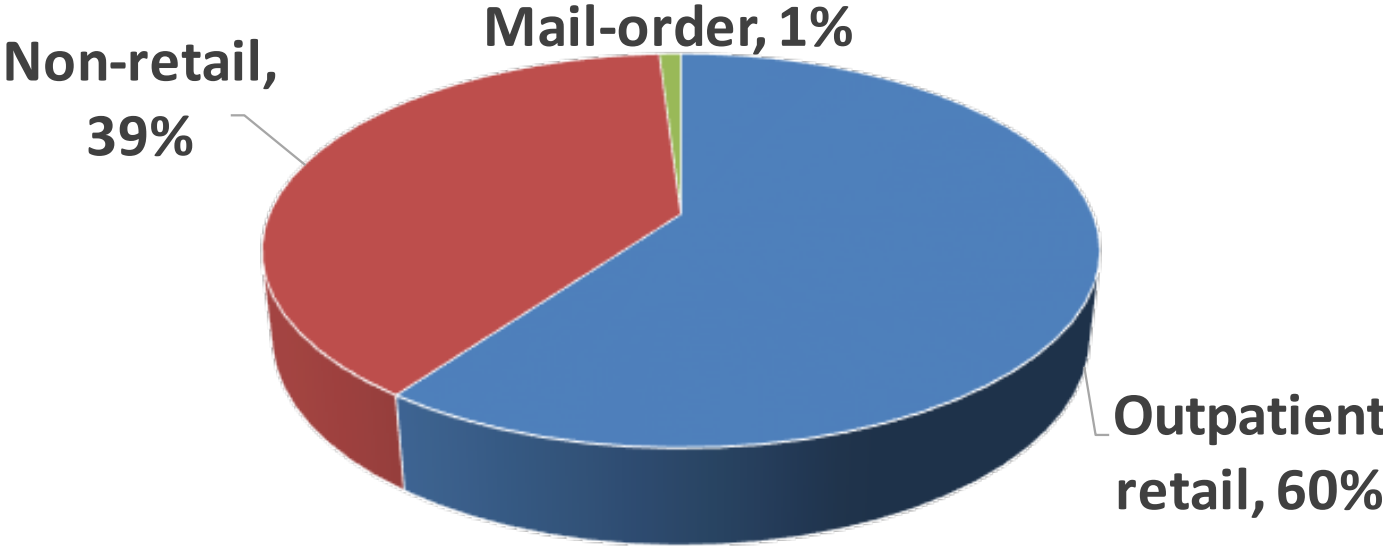
Background

- OxyContin receives pediatric indication
 - Approved in August 2015
 - For pediatric patients 11 years of age and older who tolerate a minimum daily dose of at least 20mg of oxycodone
- Best Pharmaceuticals for Children Act

Outline

- Single-ingredient oxycodone extended-release (ER) and immediate-release (IR) formulations
- Pediatric utilization of oxycodone ER and IR
- Prescriber specialty data
- Diagnoses data
- Limitations
- Post-marketing requirement (PMR) study

U.S. Sales Distribution for Single-Ingredient Oxycodone, 2018



■ Outpatient retail ■ Non-retail ■ Mail-order

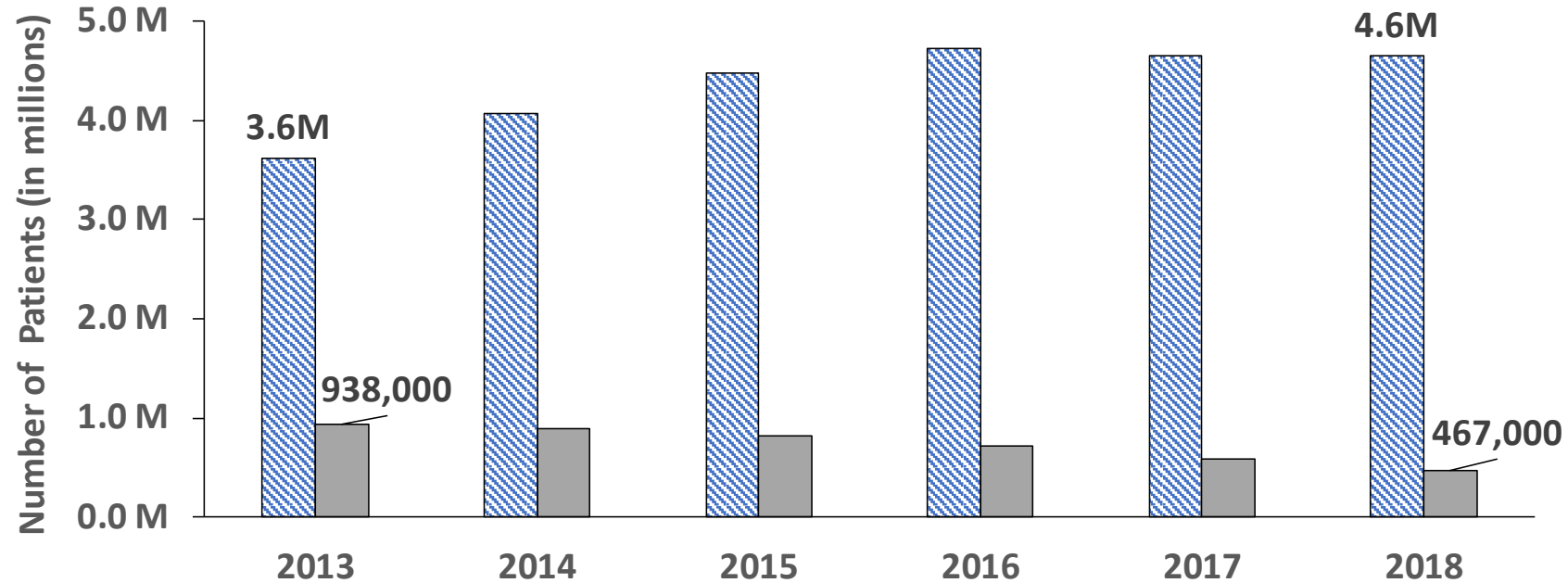
Data Source: IQVIA National Sales Perspective, 2019. Data extracted July 2019

Prescription Utilization Databases

- **IQVIA Total Patient Tracker™ (TPT)**
 - Measures the total number of unique patients from outpatient retail pharmacies
 - Data are nationally projected to provide national estimates
- **IQVIA National Prescription Audit™ (NPA)**
 - Measures prescriptions dispensed from outpatient retail pharmacies to patients
 - Data are nationally projected to provide national estimates of utilization

Oxycodone ER and IR Utilization

■ Oxycodone IR
 ■ Oxycodone ER

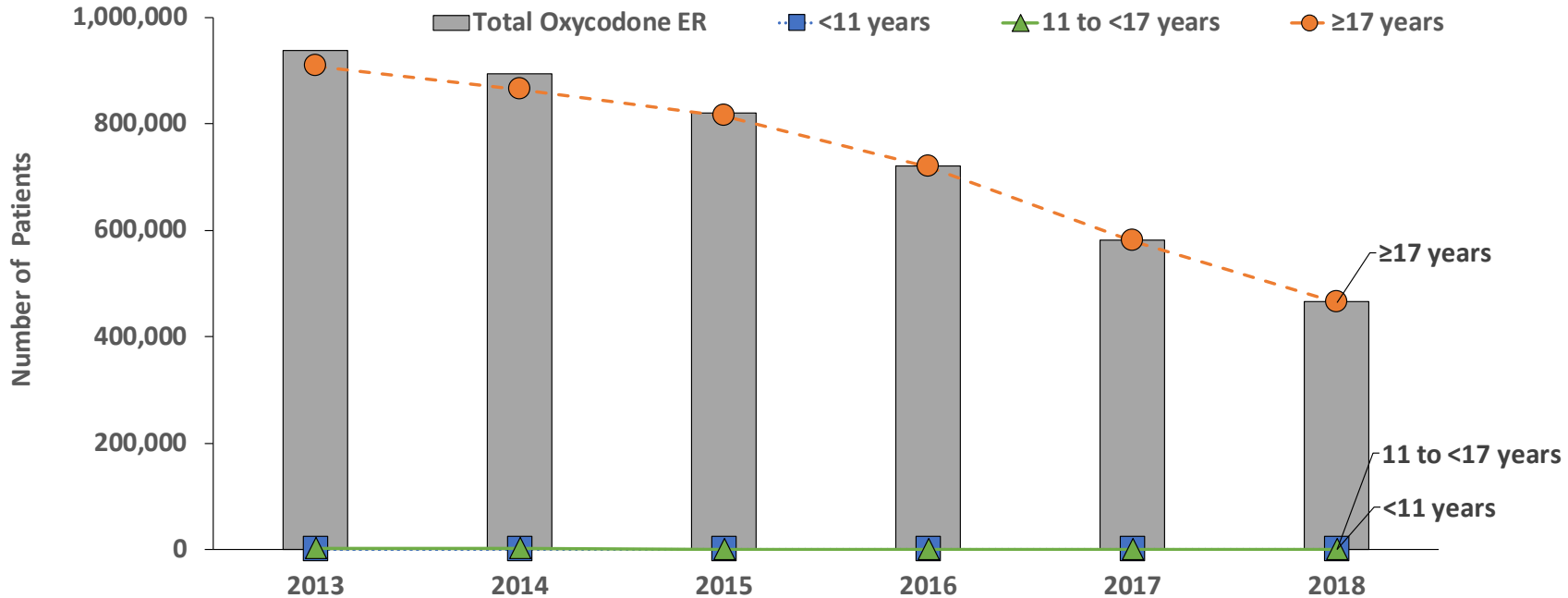


Nationally estimated number of patients who received dispensed prescriptions for single-ingredient oxycodone ER and IR from U.S. outpatient retail pharmacies, 2013 to 2018

Source: IQVIA, Total Patient Tracker™. 2013-2018. Extracted July 2019.

*Of note, there was a change in the underlying data and methodology of the proprietary database, IQVIA NPA, to manage prescription claims that are voided and/or reversed for years 2017 and 2018.

Oxycodone ER

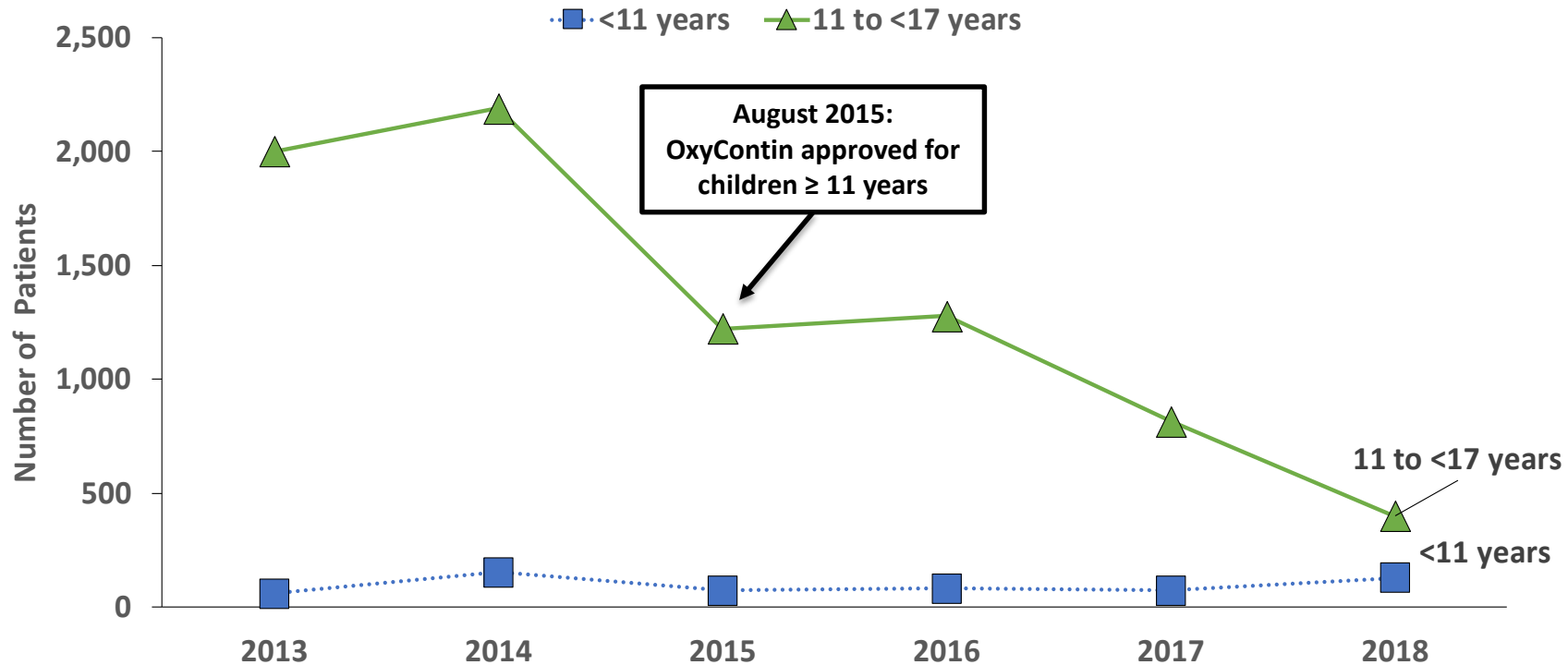


Nationally estimated number of patients who received dispensed prescriptions for single-ingredient oxycodone ER, by patient age, from U.S. outpatient retail pharmacies, 2013 to 2018

Source: IQVIA, Total Patient Tracker™. 2013-2018. Extracted July 2019.

Of note, there are changes in the underlying data and methodology of the proprietary database IQVIA NPA to account for a dynamic pharmaceutical market, including a change to manage prescription claims that are voided or reversed, prescription volumes dispensed from the retail pharmacies have been historically adjusted back to January 2017, data prior to January 2017 have not been adjusted to the new methodology. In 2018, an estimated 2% of total prescription claims for opioid analgesics dispensed from U.S. retail pharmacies appears to have been voided or reversed. *Note: Patient age groups are inclusive of all patients up to the day before their next birthday. For example, patients age 0-17 years include patients less than 18 years of age (17 years and 11 months).

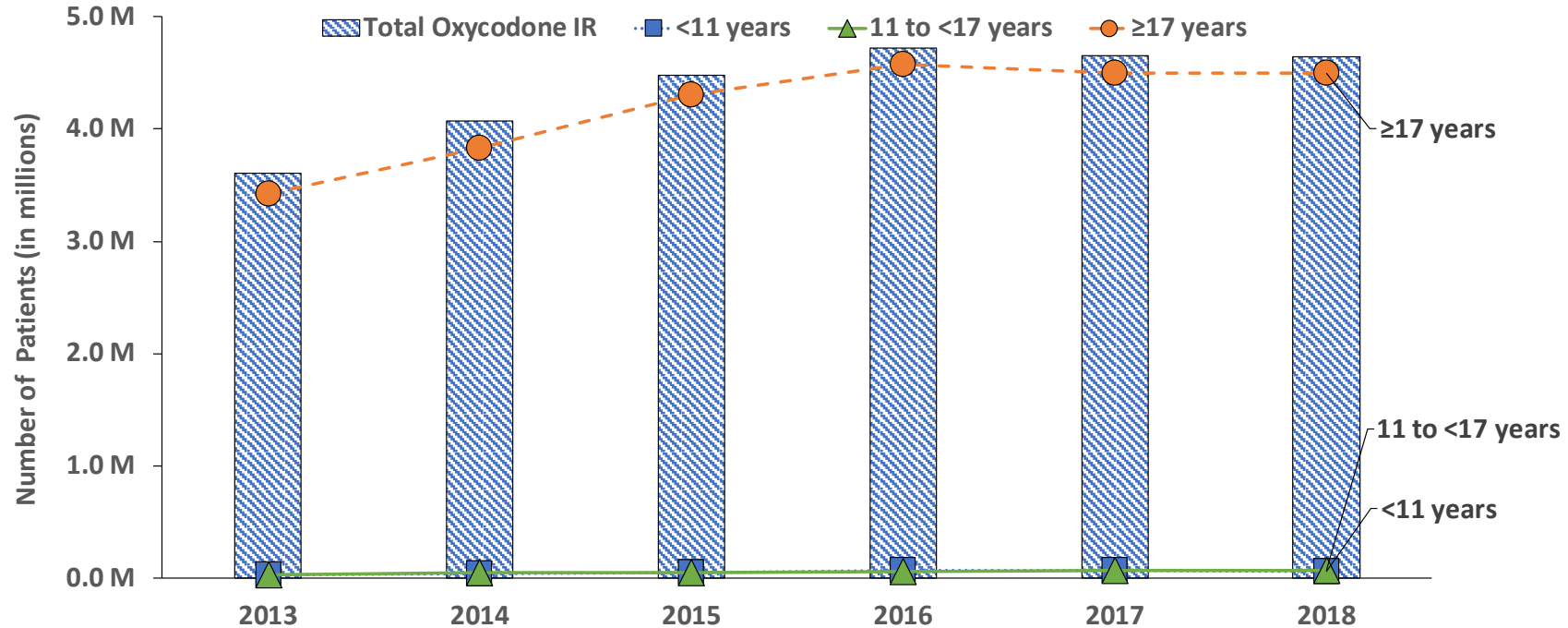
Pediatric Utilization of Oxycodone ER



Nationally estimated number of pediatric patients who received dispensed prescriptions for single-ingredient oxycodone ER from U.S. outpatient retail pharmacies, 2013 to 2018

Source: IQVIA, Total Patient Tracker™. 2013-2018. Extracted July 2019.

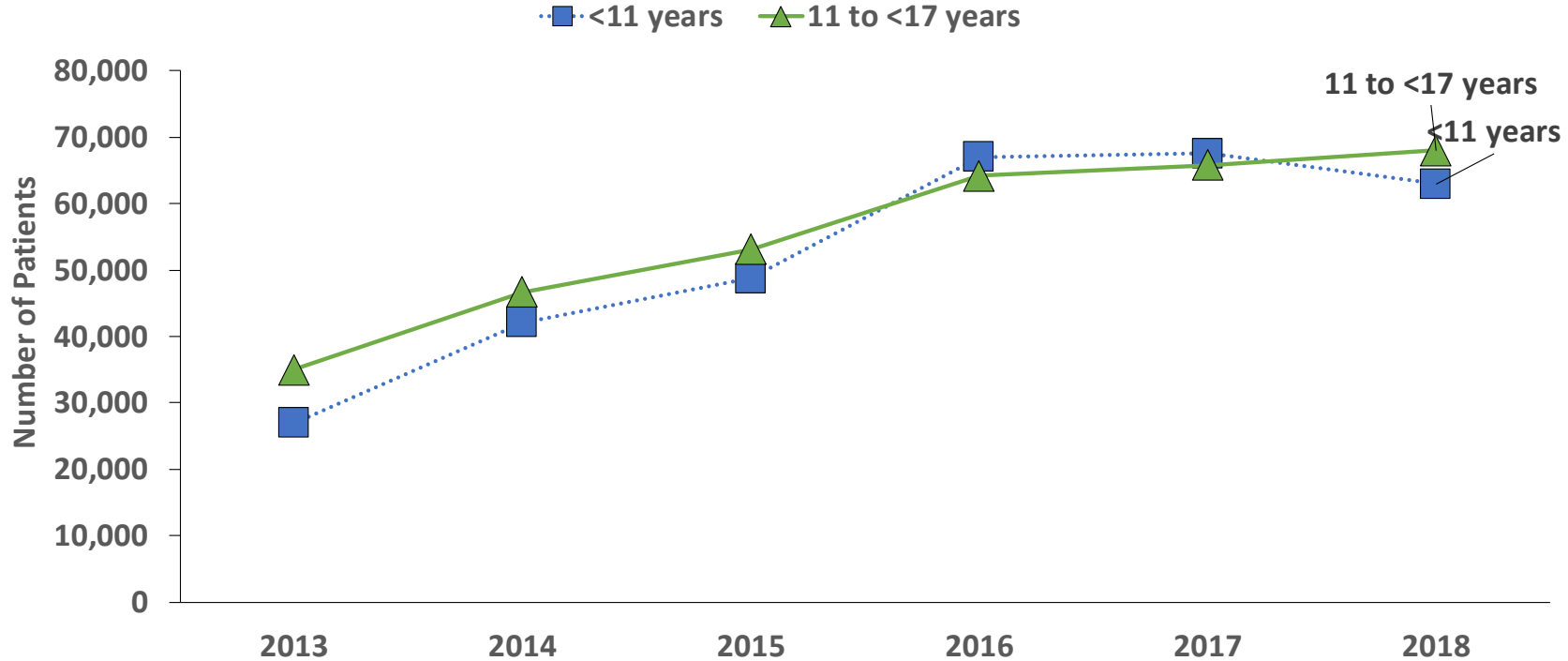
Single-Ingredient Oxycodone IR



Nationally estimated number of patients who received dispensed prescriptions for single-ingredient oxycodone IR from U.S. outpatient retail pharmacies

Source: IQVIA, Total Patient Tracker™. 2013-2018. Extracted July 2019

Pediatric Utilization of Oxycodone IR



Nationally estimated number of pediatric patients who received dispensed prescriptions for single-ingredient oxycodone IR from U.S. outpatient retail pharmacies

Source: IQVIA, Total Patient Tracker™. 2013-2018. Extracted July 2019

Top Prescribing Specialties in 2018: Pediatric Patients

- Oxycodone ER Prescriptions
 - Patient ages <11 years: Primary care* (12% of prescriptions), Pediatrics (6%)
 - Patient ages 11-<17 years: Nurse practitioners/Physician assistants (24%), Surgical specialties* (24%)
- Oxycodone IR Prescriptions
 - Patient ages <11 years: Otolaryngology (21%), Surgical specialties* (16%)
 - Patient ages 11-<17 years: Surgical specialties* (28%), Nurse practitioners/Physician assistants (22%)

Source: IQVIA, National Prescription Audit™ 2018. Extracted: August 2019.

*Primary care - family practice, general practice and internal medicine, Pediatrics-Pediatrics, internal medicine pediatrics and critical care pediatrics, Surgical specialties-cardiothoracic surgery, general surgery, neurological surgery, orthopedic surgery of the spine, orthopedic surgery, pediatric neuro surgery, plastic surgery, thoracic surgery, critical care surgery, colon and rectal surgery, cardiovascular surgery and other surgical specialties.



U.S. Office-Based Physician Survey Data

- Syneos Health Research & Insights LLC., TreatmentAnswers™ with Pain Panel
- Monthly survey of 3,200 office-based physicians
- Data are nationally projected to reflect national prescribing patterns
- Data provide insight into prescriber intent



Diagnoses Data

- No data on diagnoses associated with single-ingredient oxycodone ER use in pediatric patients was reported from 2013 to 2018
- Top diagnoses associated with oxycodone IR:
 - Patients aged 11-<17 years: management of sickle-cell disorders
 - Patients aged <11 years: dislocation of the joints at ankle, foot, and toe

Limitations

- Only dispensing patterns in the outpatient retail setting were assessed
- Diagnoses data are not necessarily linked to dispensed prescriptions
- Diagnoses data were derived from surveys of office-based practices

Post-Marketing Requirement (PMR) Study



- PMR 2923-2: drug utilization study
- Goal: evaluate pediatric use in all care settings
 - Number of prescriptions, patients
 - Strength and dose
 - Opioid tolerance status at start of therapy
 - Duration of therapy
 - Indication

Post-Marketing Requirement (PMR) Study



- PMR 2923-2 issued August 2015
- Protocol and Statistical Analysis Plan finalized May 2018
- Sponsor continues to work to provide
 - Robust results for opioid tolerance status
 - Indication among inpatient and outpatient use
 - Patterns of inpatient use
- Final report is due March 2020

Conclusions

- Pediatric use of single-ingredient oxycodone ER remains low
- Pediatric use of single-ingredient oxycodone IR increased
- Oxycodone ER prescriptions for patients 11-<17 years were written by nurse practitioners and physician assistants, followed by surgical specialties
- No data on diagnoses associated with oxycodone ER reported for pediatric patients in survey data
- Additional data requested under PMR are expected March 2020



Thank you



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