

Pediatric Utilization Patterns of Montelukast, 2014-2018

**Ibrahim T Ibrahim, PharmD, MPH, BCPS
Drug Utilization Analyst
Division of Epidemiology II
Office of Surveillance and Epidemiology
FDA Center for Drug Evaluation and Research**

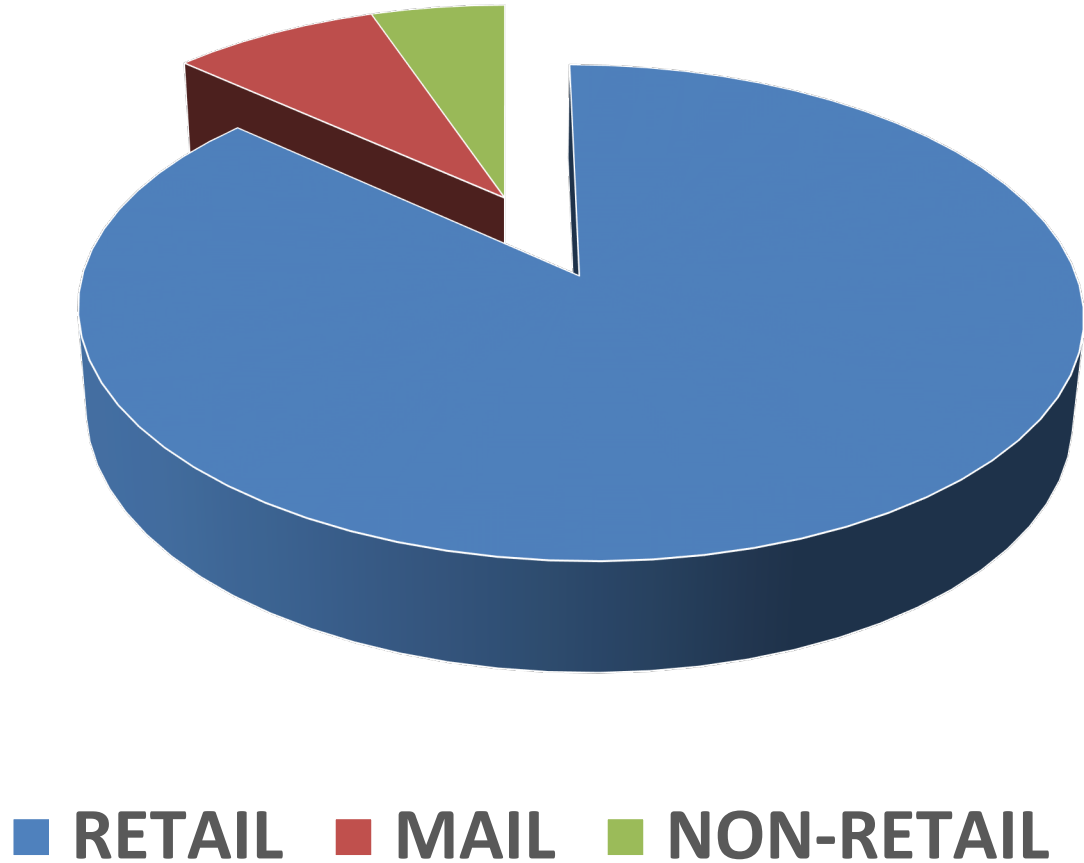
September 27, 2019

Meeting of the Pediatric Advisory Committee

Outline

- National sales distribution data
- Outpatient retail pharmacy utilization data
 - Prescription and patient level data
 - Top prescriber specialties
- Office-based physician surveys
 - Top diagnoses
- Limitations
- Summary

U.S. Sales Distribution for Montelukast 2018



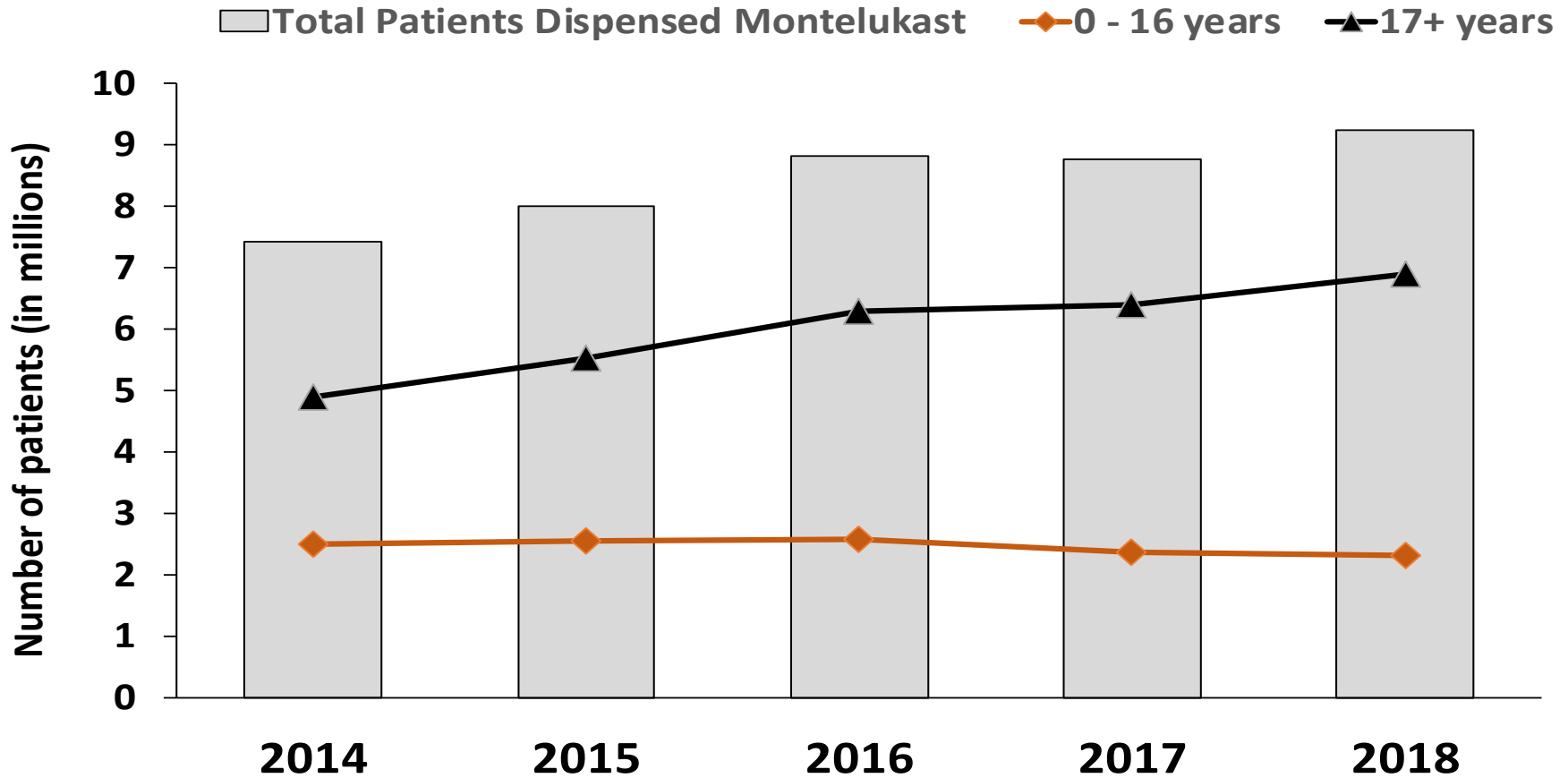
Source: IQVIA, National Sales Perspectives™. Year 2018. Data extracted March 2018.

Prescription Utilization Databases



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

Montelukast Utilization

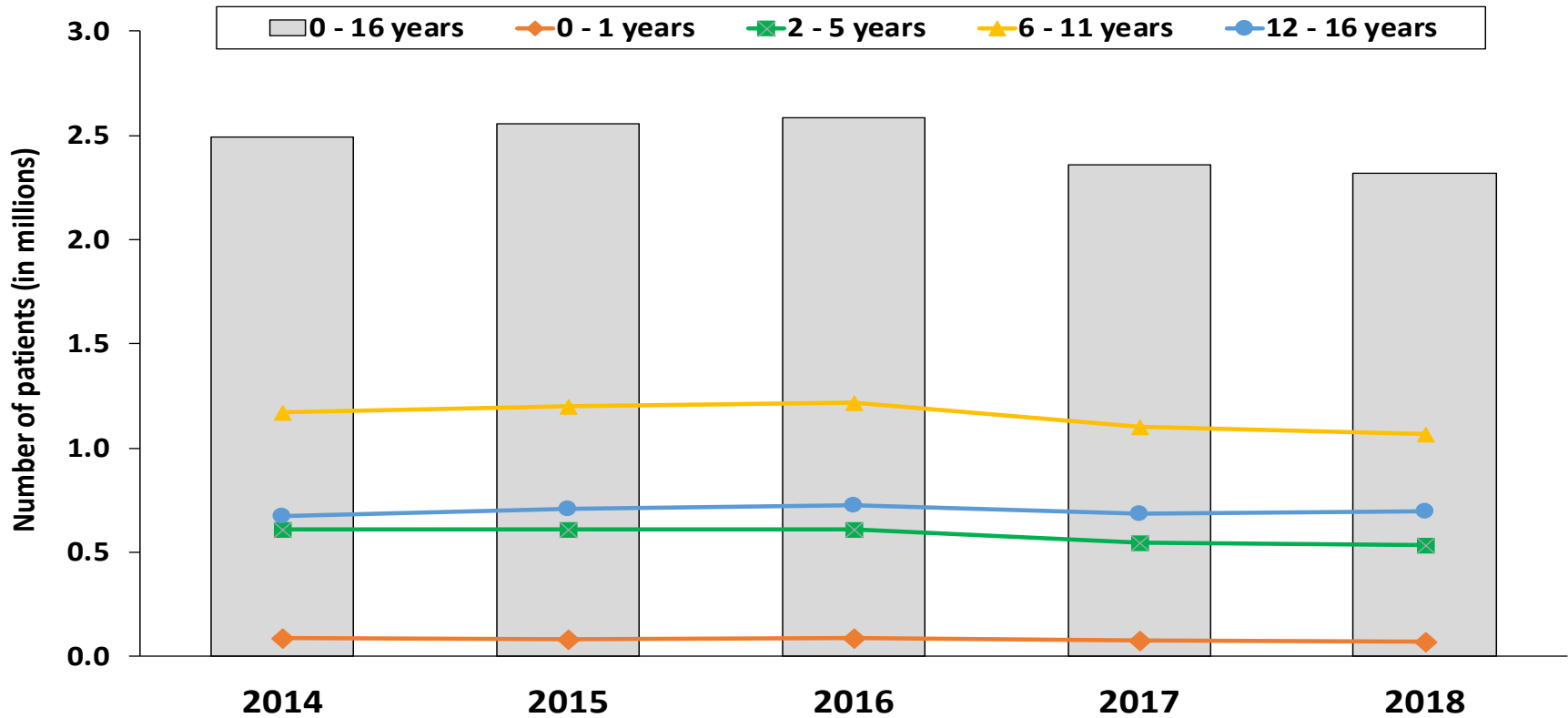


National estimates of patients* who received prescriptions dispensed for montelukast, by patient age, from U.S. outpatient retail pharmacies, 2014-2018**

Data Source: IQVIA Total Patient Tracker™. 2014-2018. Data extracted June, 2019. *Note: Patient age groups are inclusive of all patients up to the day before their next birthday. For example, patients age 0-16 years include patients less than 17 years of age (16 years and 11 months).

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. Because TPT patient data are derived from NPA prescription data, projected patient estimates have been adjusted and restated in the database back to January 2017, data prior to 2017 remain unadjusted. As a result, a trend break occurs between the 2016 and 2017 patient estimates who received prescriptions dispensed from retail pharmacies.

Pediatric Montelukast Utilization



National estimates of pediatric patients* (0-16 years old) who received prescriptions dispensed for montelukast, stratified by patient age, from U.S. outpatient retail pharmacies, 2014-2018**

*Note: Patient age groups are inclusive of all patients up to the day before their next birthday. For example, patients age 0-16 years include patients less than 17 years of age (16 years and 11 months).**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. Because TPT patient data are derived from NPA prescription data, projected patient estimates have been adjusted and restated in the database back to January 2017, data prior to 2017 remain unadjusted. As a result, a trend break occurs between the 2016 and 2017 patient estimates who received prescriptions dispensed from retail pharmacies.**Data Source: IQVIA Total Patient Tracker™. 2014-2018. Data extracted June, 2019.

Top Prescribing Specialties



	2018	
	TRxs	%
Total Prescriptions Dispensed for Montelukast	35,400,841	100.0%
Family Practice/General Practice/Internal Medicine	12,126,035	34.3%
Physician Assistants/Nurse Practitioners	8,120,006	22.9%
Pediatrics/Internal Medicine Pediatrics	3,968,325	11.2%
Osteopathic Medicine	3,171,214	9.0%
Allergy	3,097,499	8.8%
Pulmonary Diseases	1,479,090	4.2%
Otolaryngology	1,084,295	3.1%
Pulmonary Critical Care	732,305	2.1%
Geriatrics	134,765	0.4%
All other Specialties	1,487,307	4.2%

Top prescribing specialties of montelukast (all ages) by number of prescriptions dispensed from U.S. outpatient retail pharmacies, 2018



U.S. Office-Based Physician Survey Data

- Syneos Health Research & Insights LLC., TreatmentAnswers™ with Pain Panel
- Monthly survey of 3,200 **office-based physicians** representing 30 specialties
- Data are projected to reflect national prescribing patterns
- Data provide insight into prescriber intent



Top Diagnosis Associated with Montelukast use in Pediatric Patients

- **<2 years old**
 - Cough (45%)
 - Vasomotor and allergic rhinitis (33%)
 - Asthma (20%)
- **2 - 5 years old**
 - Asthma (56%)
 - Vasomotor and allergic rhinitis (29%)
 - Cough (9%)
- **6 - 11 years old**
 - Asthma (43%)
 - Vasomotor and allergic rhinitis (38%)
 - Encounter for general adult medical examination without abnormal findings (7%)
- **12-16 years old**
 - Asthma (58%)
 - Vasomotor and allergic rhinitis (19%)
 - Cough (6%)

Top diagnoses* associated with the use of Montelukast in pediatric patients (<2, 2-5, 6-11, 12-16 years old) as reported by U.S. office-based physician surveys, 2018.

Source: Syneos Health Research & Insights LLC., TreatmentAnswers™. 2014-2018. Data extracted February 2019. *Diagnosis data are not directly linked to dispensed prescriptions but are obtained from surveys of a sample of 3,200 office-based physicians reporting on patient activity during one day per month. Because of the small sample sizes with correspondingly large confidence intervals, the drug use mentions <100,000 are too low to provide reliable national estimates for the diagnoses and therefore, preclude meaningful interpretation of data trends. Patient age groups are inclusive of all patients up to the day before their next birthday. For example, patients aged 0-16 years include patients less than 17 years old (16 years and 11 months).

Limitations



- Data utilization analyzed is only from the outpatient retail pharmacy
 - may not apply to other healthcare settings
- Diagnoses data are not necessarily linked to dispensed prescriptions
- Diagnoses data were derived from surveys of office-based physician practices

Summary



- Montelukast is primarily utilized in the outpatient retail setting
- Estimated 2.3 to 2.5 million pediatric patients annually received montelukast prescription
- Pediatric use of montelukast was associated with the diagnoses of asthma, followed by allergic rhinitis and cough in 2018

Thank You

