

Testosterone Utilization Patterns Among Pediatric Patients

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FDA Pediatric Advisory Committee

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Outline

- Database descriptions
- Methods/Results
 - U.S. national estimates: number of male patients with dispensed testosterone prescriptions
 - Sample of commercially-insured patients: diagnoses proximal to testosterone initiation
- Conclusions

Database descriptions

- IQVIA, Total Patient Tracker™
 - U.S. national estimates for the number of patients with prescriptions dispensed from U.S. outpatient retail pharmacies
- IQVIA, Health Plan Claims Data™
 - Administrative health care claims for a sample of commercially-insured patients to analyze diagnoses proximal to testosterone initiation

Methods: National Estimates

- Testosterone prescriptions dispensed from U.S. outpatient retail pharmacies
- 4 years of data in 12-month increments from September 2013 to August 2017
- Male patients by age group
 - ≤ 13 years old, 14-17 years old

Male Patients Dispensed Testosterone



| | Year ending Aug 2014 | | Year ending Aug 2015 | | Year ending Aug 2016 | | Year ending Aug 2017 | |
|-------------------|----------------------|-----------|----------------------|-----------|----------------------|-----------|----------------------|-----------|
| | Patients (N) | Share (%) | Patients (N) | Share (%) | Patients (N) | Share (%) | Patients (N) | Share (%) |
| All male patients | 1,648,037 | 100% | 1,386,561 | 100% | 1,347,231 | 100% | 1,413,355 | 100% |
| 0-17 years old | 6,308 | <1% | 7,232 | <1% | 6,847 | <1% | 7,407 | <1% |
| 0-13 years old | 1,699 | 27% | 1,826 | 25% | 1,448 | 21% | 1,636 | 22% |
| 14-17 years old | 4,609 | 73% | 5,406 | 75% | 5,399 | 79% | 5,771 | 78% |

Nationally estimated number of young male patients dispensed testosterone prescriptions from U.S. outpatient retail pharmacies

Source: IQVIA Total Patient Tracker™. September 2013 – August 2017. Summing patient counts across time periods or age groups is not advisable due to patients aging during the study period.

Diagnoses among pediatric patients
with ≥ 1 year of testosterone therapy

Methods: Diagnosis Analysis

- Male patients ≤ 19 years old with ≥ 1 year of therapy:
 - Patient had 5 or more testosterone claims AND either (a) or (b) below
 - (a) Continuous testosterone therapy of 1 year or longer
 - (b) 1+ year between first and last testosterone claim and an average of 2+ testosterone claims per year
- Any *diagnosis of interest* in medical claims
 - Searched 1 year prior to through 1 month following testosterone initiation
- Aggregated data 2009 through 2016
- Included all testosterone formulations (e.g., IV, transdermal)
- Included all outpatient settings of care (e.g., retail pharmacies, clinics, doctor's offices)

Testosterone Diagnoses Among Young Male Patients With ≥ 1 year Testosterone Therapy



| Age cohort | ≤ 13 years (N=299) | 14-17 years (N=944) | 18-19 years (N=406) |
|------------------|---|---|---|
| Diagnostic codes | <ul style="list-style-type: none"> • Other testicular hypofunction – 34% • Delay in sexual development and puberty, not elsewhere classified – 33% • Lack of expected normal physiological development – 31% • Klinefelter syndrome – 18% | <ul style="list-style-type: none"> • Other testicular hypofunction – 36% • Delay in sexual development and puberty, not elsewhere classified – 35% • Lack of expected normal physiological development – 25% • Klinefelter syndrome – 17% | <ul style="list-style-type: none"> • Other testicular hypofunction – 55% • Other anterior pituitary disorders – 16% • Panhypopituitarism – 15% • Klinefelter syndrome – 15% |

Most prevalent diagnostic codes of interest among a sample of 1,649 commercially-insured male patients aged 19 years or younger with ≥ 1 year testosterone therapy

Source: IQVIA™ Health Plan Claims Data. January 2009 – December 2016. NEC = Not Otherwise Classified. Diagnostic codebs of interest were captured on claims occurring 1 year prior to or 2 months following the patient's initial testosterone claim. Sums may add to more than the total due to patients having more than one diagnosis of interest.

Conclusions

- Pediatric male patients comprised less than 1% of male patients who received testosterone from retail pharmacies
 - About 75% were 14-17 years old (annual range 73-79%)
 - Use in clinics or medical offices was not captured
- Among pediatric male patients with long-term use, the most prevalent diagnoses were testicular hypofunction or delayed puberty
 - Many diagnosis codes not informative enough to describe etiologies
 - Use in clinics or medical offices was captured



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