Tetracycline Drug Class Post-Implementation Review

Implemented August 2017

Selected Slides from Feb 2017 Review

Clinical Conclusions from February 2017 Class Review Minutes

- Tetracycline, minocycline, and doxycycline are all effective in the treatment of moderate to severe acne and rosacea.
- Professional treatment guidelines for papulopustular rosacea recommend doxycycline 50 mg to 100 mg, minocycline 50 mg to 100 mg, or doxycycline 40 mg IR/DR (Oracea) as second-line therapy following topical medications, but there are concerns of conflict of interest with the guideline's authors.
- A 2015 Cochrane review evaluating doxycycline for treating rosacea found no significant difference in effectiveness between doxycycline 100 mg and 40 mg IR/DR (Oracea). There were significantly fewer adverse effects with the 40 mg lower dose; however, the results were based on low quality evidence and the clinical relevance of these results is questionable. There was high quality evidence to support efficacy of generic doxycycline 100 mg.

Clinical Conclusions from February 2017 Class Review Minutes

- Solodyn was originally developed as an extended-release (ER) minocycline formulation to reduce potential vestibular adverse effects associated with rapid absorption of generic minocycline IR formulations. However, pharmacokinetic studies showed the absorption profile for Solodyn does not differ significantly from that of minocycline IR.
- There are no head-to-head trials comparing the efficacy or safety of minocycline ER (Solodyn) with generic minocycline IR products for treating acne. A Cochrane review from 2015 concluded there was no data to support minocycline ER formulations are safer than standard minocycline IR preparations.
- Overall, there is little evidence to support advantages of the newer doxycycline and minocycline products over the traditional generic formulations in terms of salt (monohydrate versus hyclate), dosage form (tablet versus capsule versus scored tablets), release mechanisms (IR versus ER versus DR), or dosing strategy (1 mg/kg dosing with minocycline ER versus traditional 50 mg or 100 mg dosing).

From Feb 2017 review

Tetracyclines, BRAND

BRAND NAME	GENERIC NAME	STRENGTH (mg)	SALT	GENERICS
Acticlate	**doxycycline**	**75, 150**	**Hyclate**	**NO**
Doryx MPC		**60*, 120***		
Solodyn	**minocycline**	**55*, 65*, 80*, 90*, 105*, 115***	HCl	
Demeclocyclin	demeclocycline	150, 300	HCl	YES
Adoxa	doxycycline	150	Monohydrate	
Monodox		100		
Oracea		40*		
Doryx		50*, 100*, 150*, 200*	Hyclate	
Targadox		50		
Vibramycin		50, 100		
Vibra-tabs		100		
Minocin	minocycline	50, 75, 100	HCl	
Achromycin V, Sumycin	tetracycline	250, 500	HCl	

*Delayed Release

Tetracyclines, GENERIC

BRAND NAME	GENERIC NAME	STRENGTH (mg)	SALT
Declomycine	demeclocycline	150, 300	HCL
Doxycycline IR-DR	doxycycline	40*	Hyclate
Doxycycline		50, 50*,75*, 100, 100*,150*, 200*	
Morgidox		50, 100	
Doxycycline		50, 75, 100, 150	Monohydrate
Mondoxyne NL		75, 100	
Minocycline ER	minocycline	45*, 90*, 135*	HCL
Minocycline		50, 75, 100	
Achromycin V, Sumycin, Tetracycline	tetracycline	250, 500	HCL

*Delayed Release

Source: PDTS, Longitudinal File, Prime Vendor File, MCPF, WAC File
Date Range: 1 Jan 2015 - 31 Oct 2016

"Common" versus "Boutique"

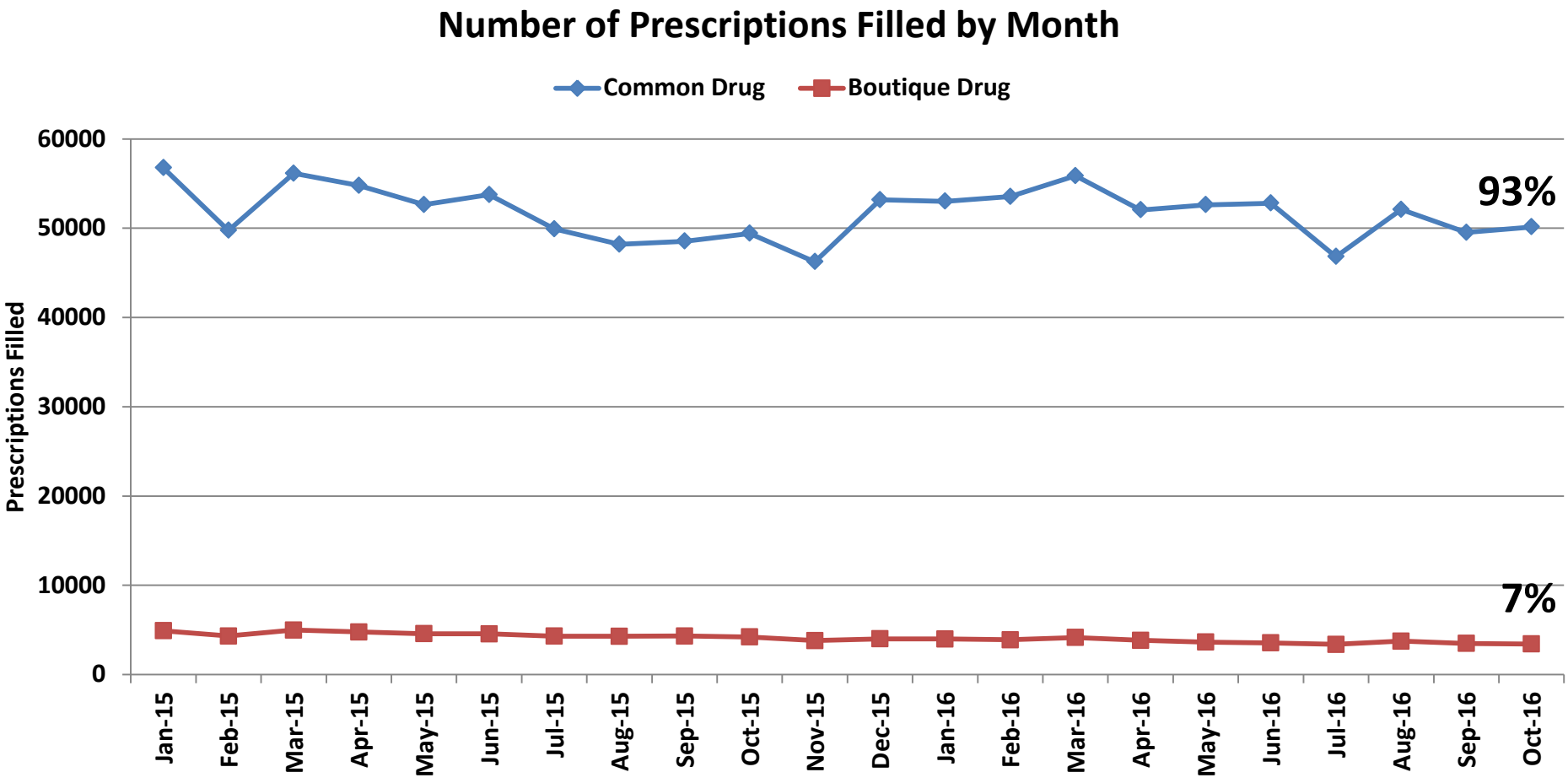
- "Common" Drugs
  - Lower cost per unit compared to other agents in the class
  - Common usage compared to other agents in the class
  - Standard dosage forms/strengths compared to other agents in the class
- "Boutique" Drugs
  - High cost per unit compared to other agents in the class
  - Niche/atypical usage compared to other agents in the class
  - Unusual dosage forms/strengths compared to other agents in the class

	RX	TSIC (RA)	Blended Cost/RX
"Common"	93%	56%	$70
"Boutique"	7%	44%	$644

Source: PDTS, Longitudinal File, Prime Vendor File, MCPF, WAC File
Date Range: 1 Jan 2015 - 31 Oct 2016

From Feb 2017 review

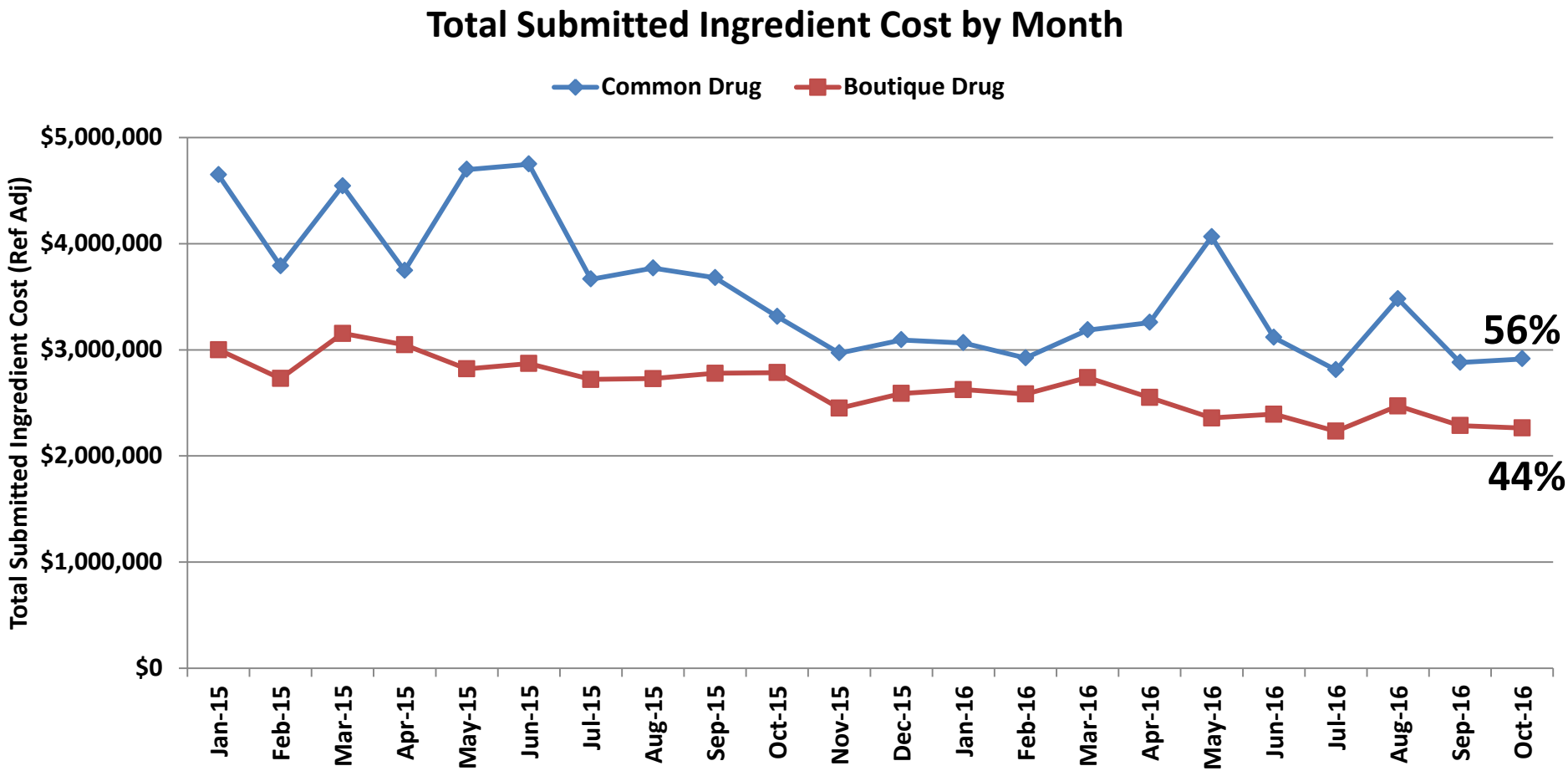
Overall Utilization
"Common" versus "Boutique"



Source: PDTS, Longitudinal File, Prime Vendor File, MCPF, Formulary Strategy Dataset, ESI DoD, FY16Q3
Date Range: 1 Jan 2015 - 31 Oct 2016

From Feb 2017 review

Overall Cost
"Common" versus "Boutique"

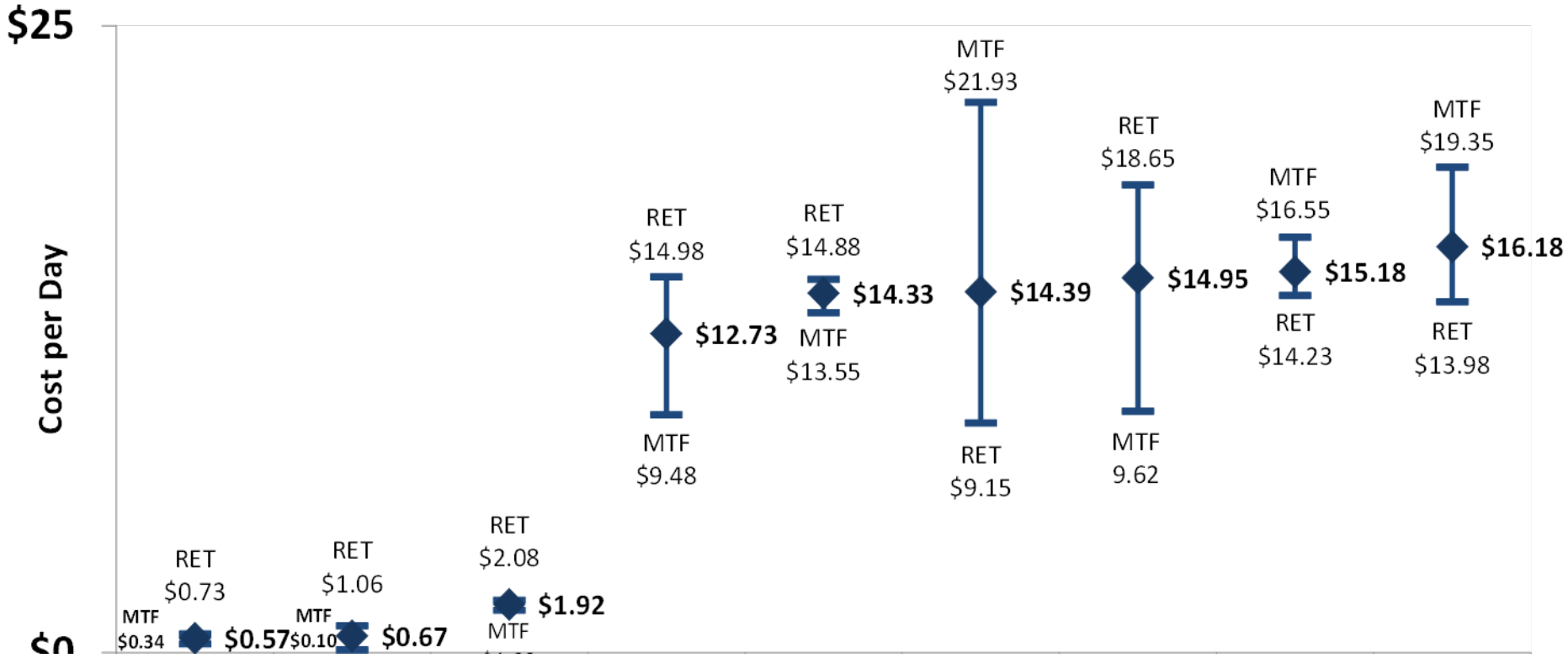


Source: PDTS, Longitudinal File, Prime Vendor File, MCPF, Formulary Strategy Dataset, ESI DoD, FY16Q3
Date Range: 1 Jan 2015 - 31 Oct 2016

From Feb 2017 review

Standardized Market Share
MTF 35% Retail 59% Mail 6%

Generics - CURRENT

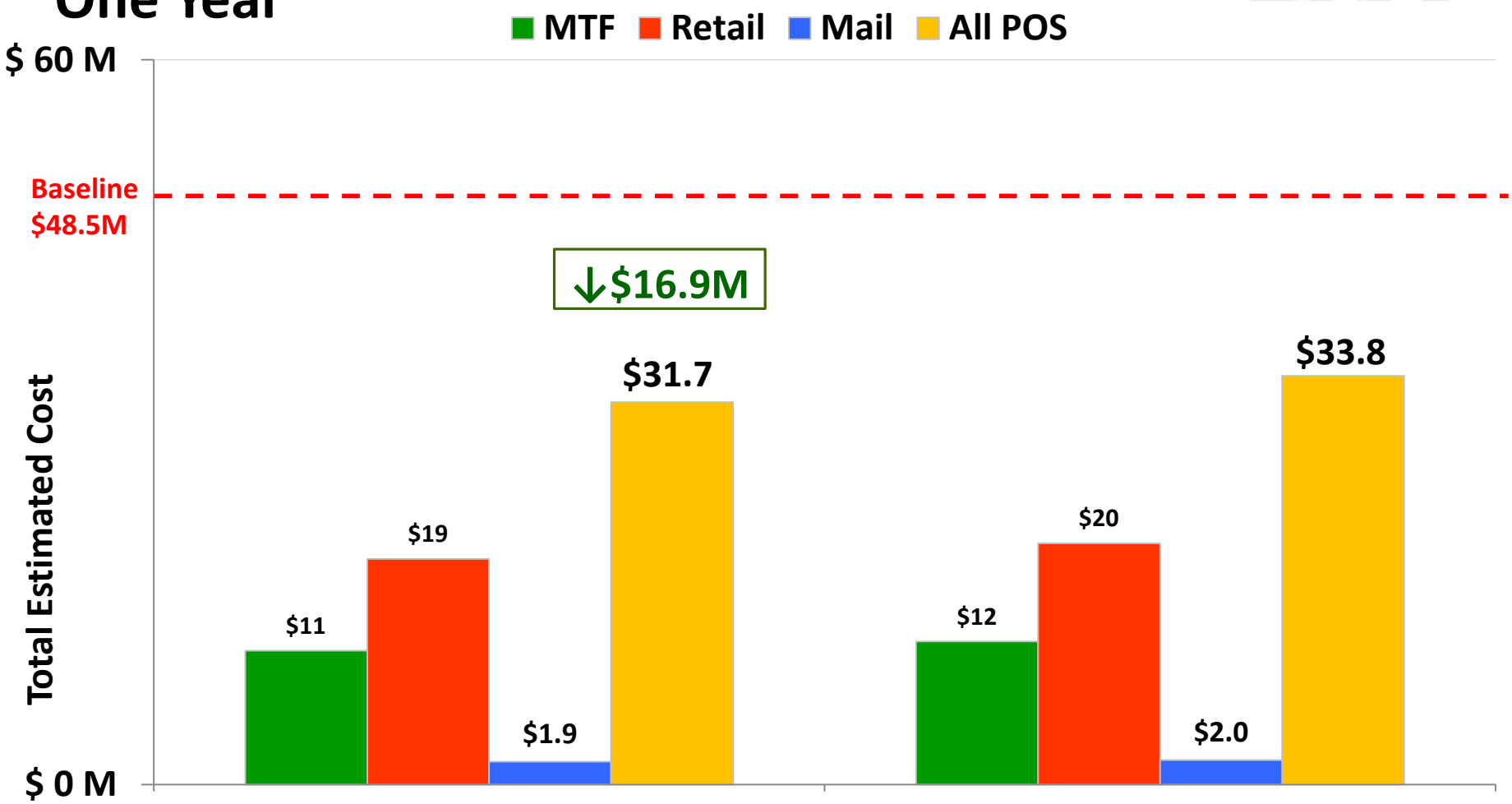


Source: PDTS, Longitudinal File, Prime Vendor File, MCPF, WAC File
Date Range: 1 Jan 2015 - 31 Oct 2016

BIA Model Results

From Feb 2017 review

One Year



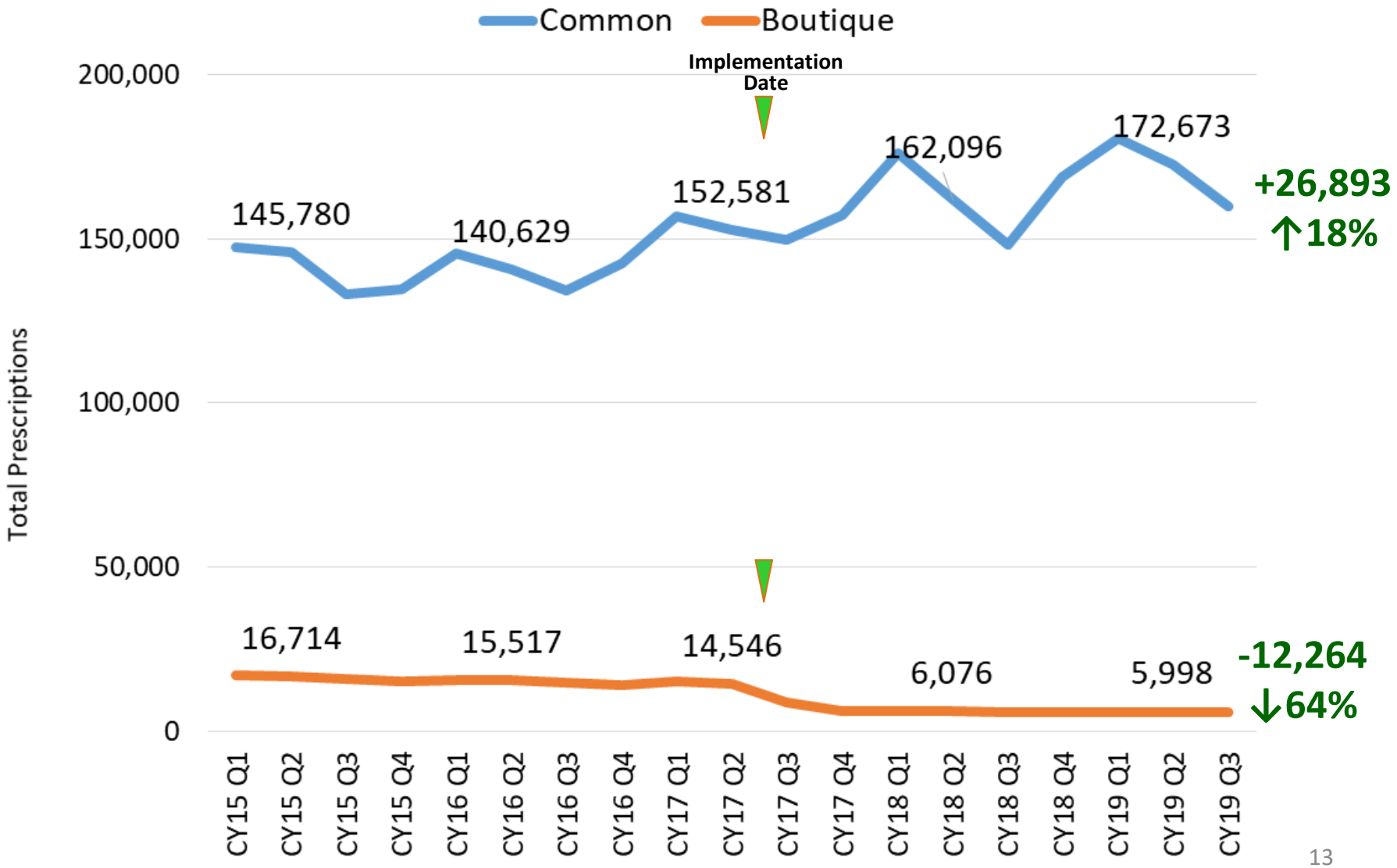
BEFORE	"Common" UF	"Common" UF
AFTER	"Boutique" NF	"Boutique" UF
SAVINGS	$16.9M	$14.7M

Tetracycline - designated UF/exempt from step therapy
Demeclocycline - designated UF/exempt from step therapy

Post-Implementation Results

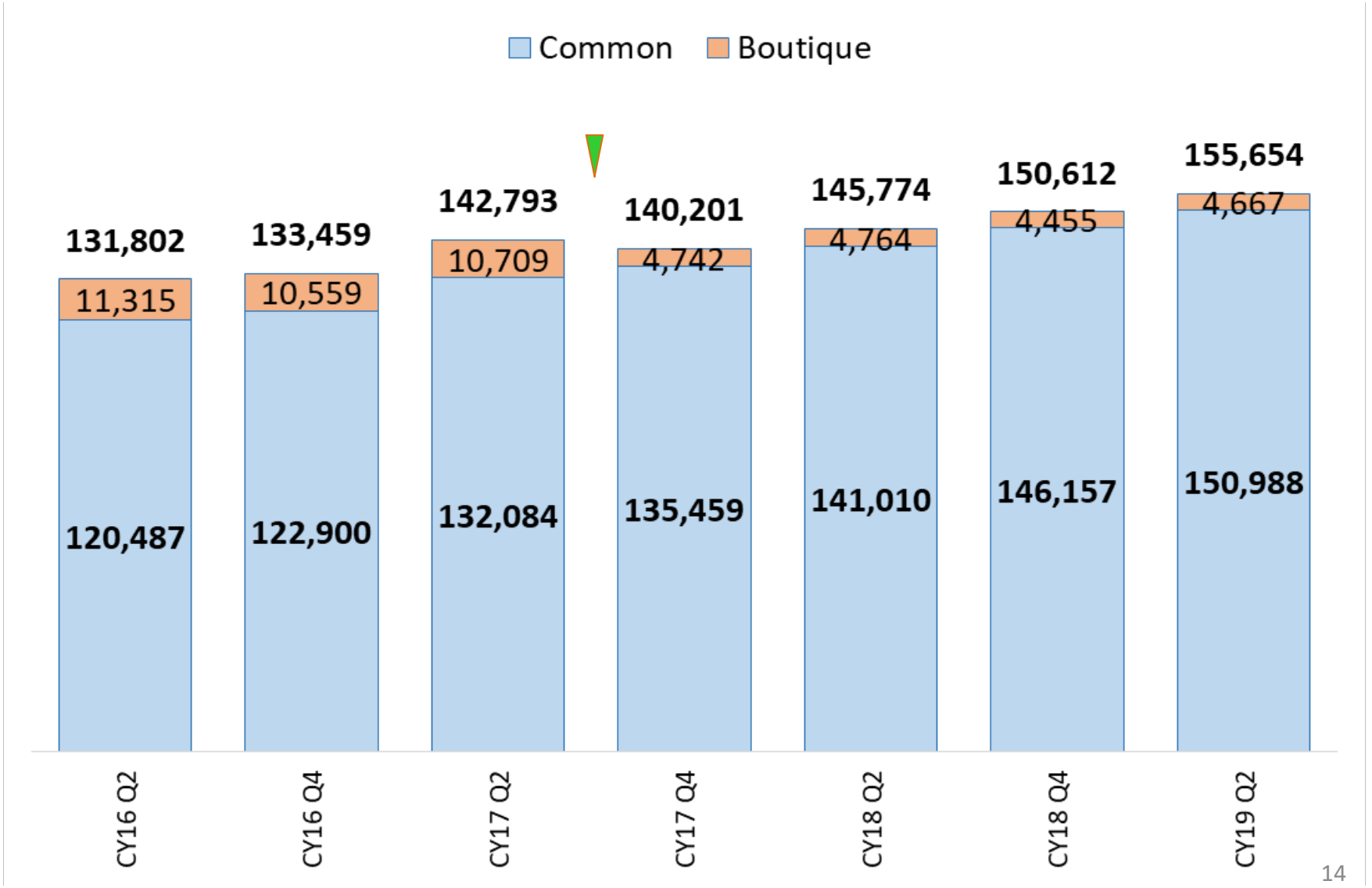
Implemented CY17Q3 (Aug 2017)

Tetracyclines
Total Prescriptions Dispensed



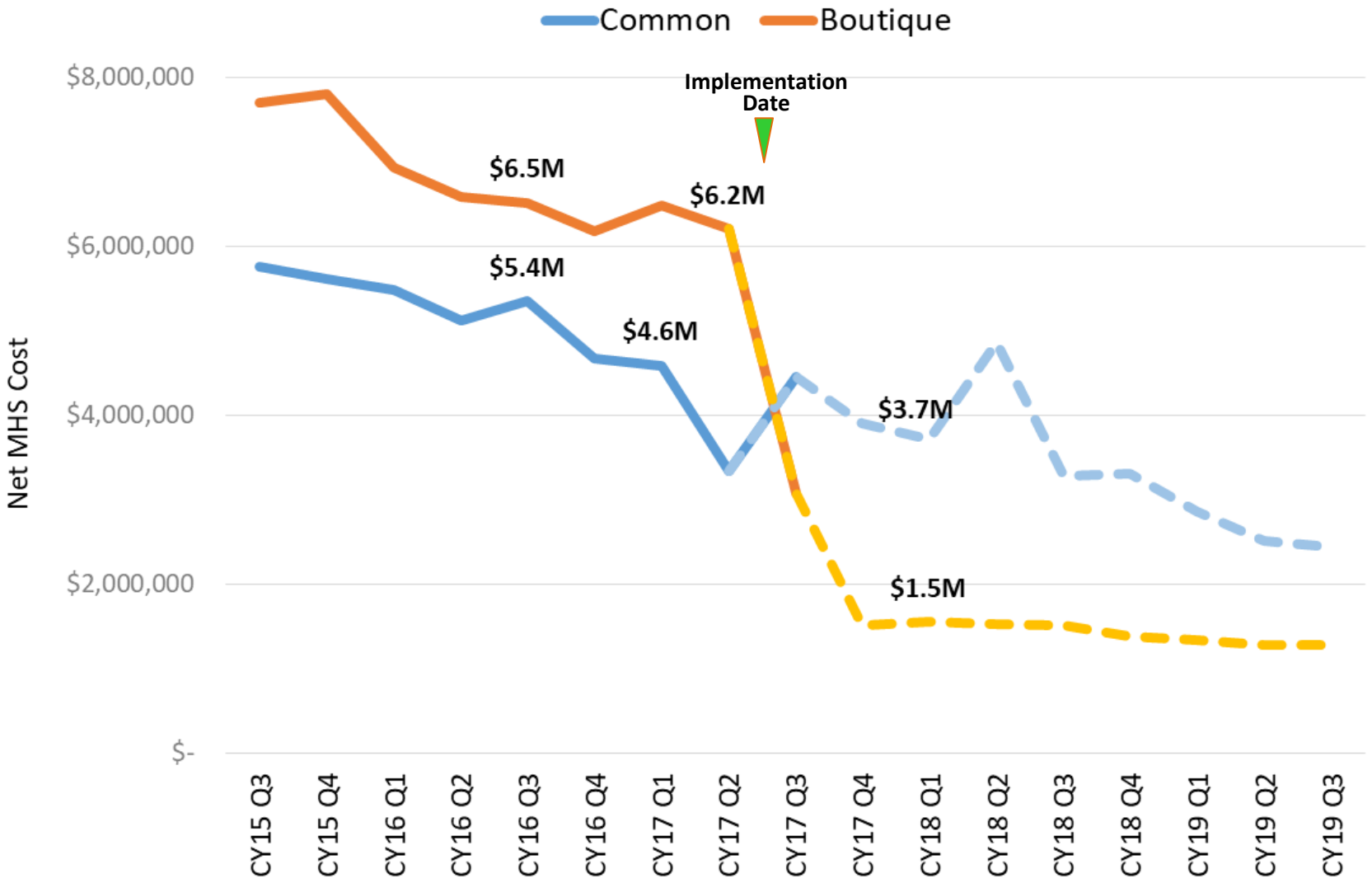
Source: PDTS. Excludes patients with other health insurance.

Tetracycline Class Review
Total Patient Count for Selected Quarters



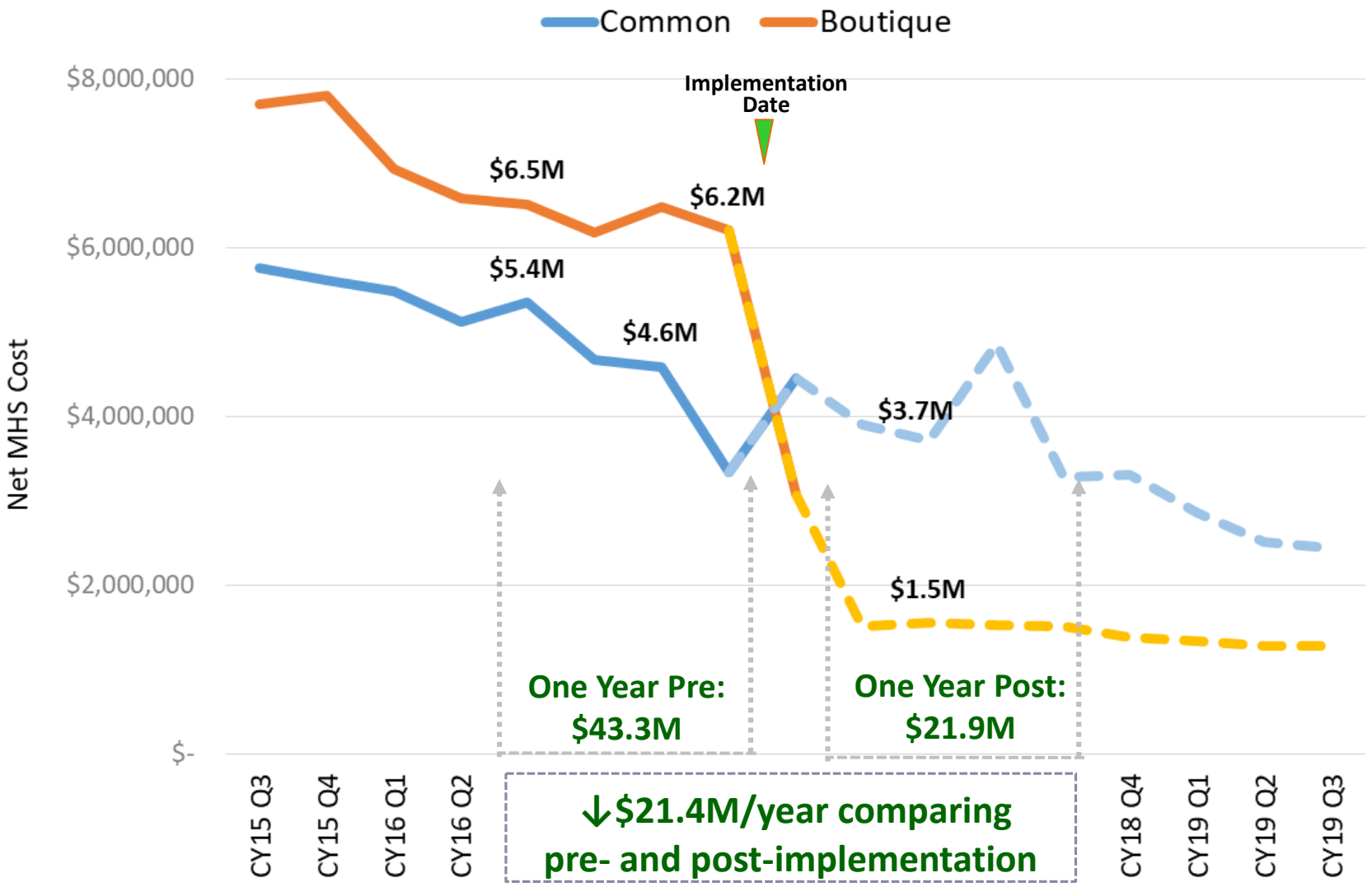
Source: PDTS. Excludes patients with other health insurance.

Tetracyclines
Net MHS Cost



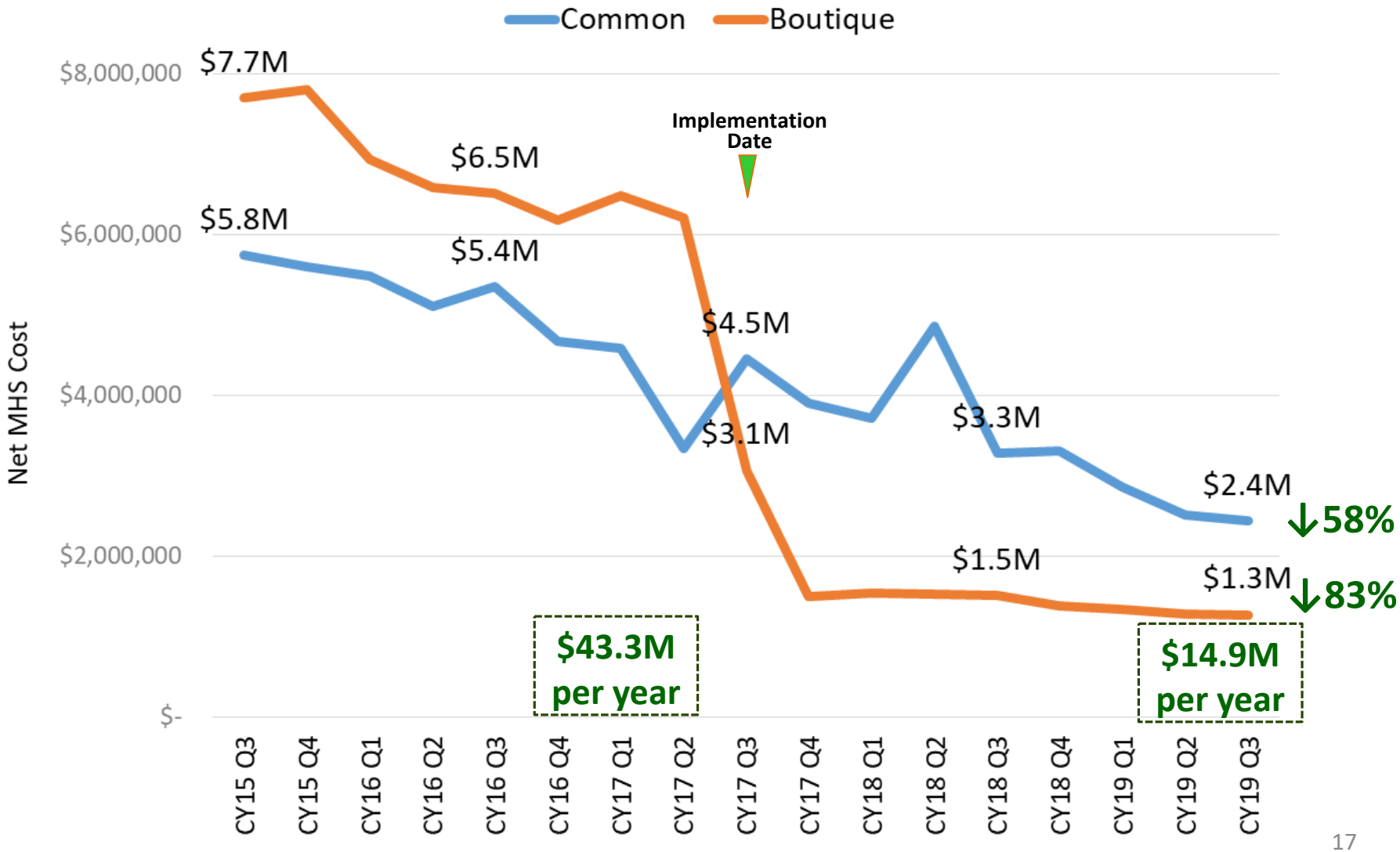
Source: PDTS. Excludes patients with other health insurance.

Tetracyclines
Net MHS Cost



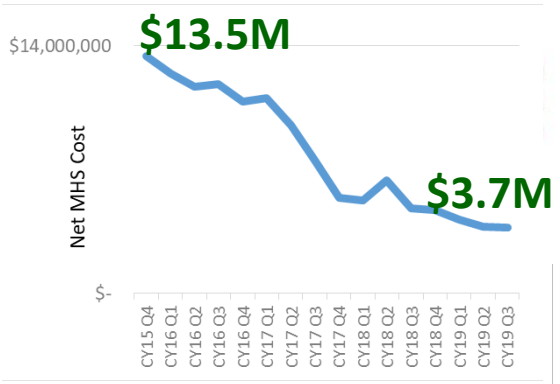
Source: PDTS. Excludes patients with other health insurance.

Tetracyclines
Net MHS Cost



Source: PDTS. Excludes patients with other health insurance.

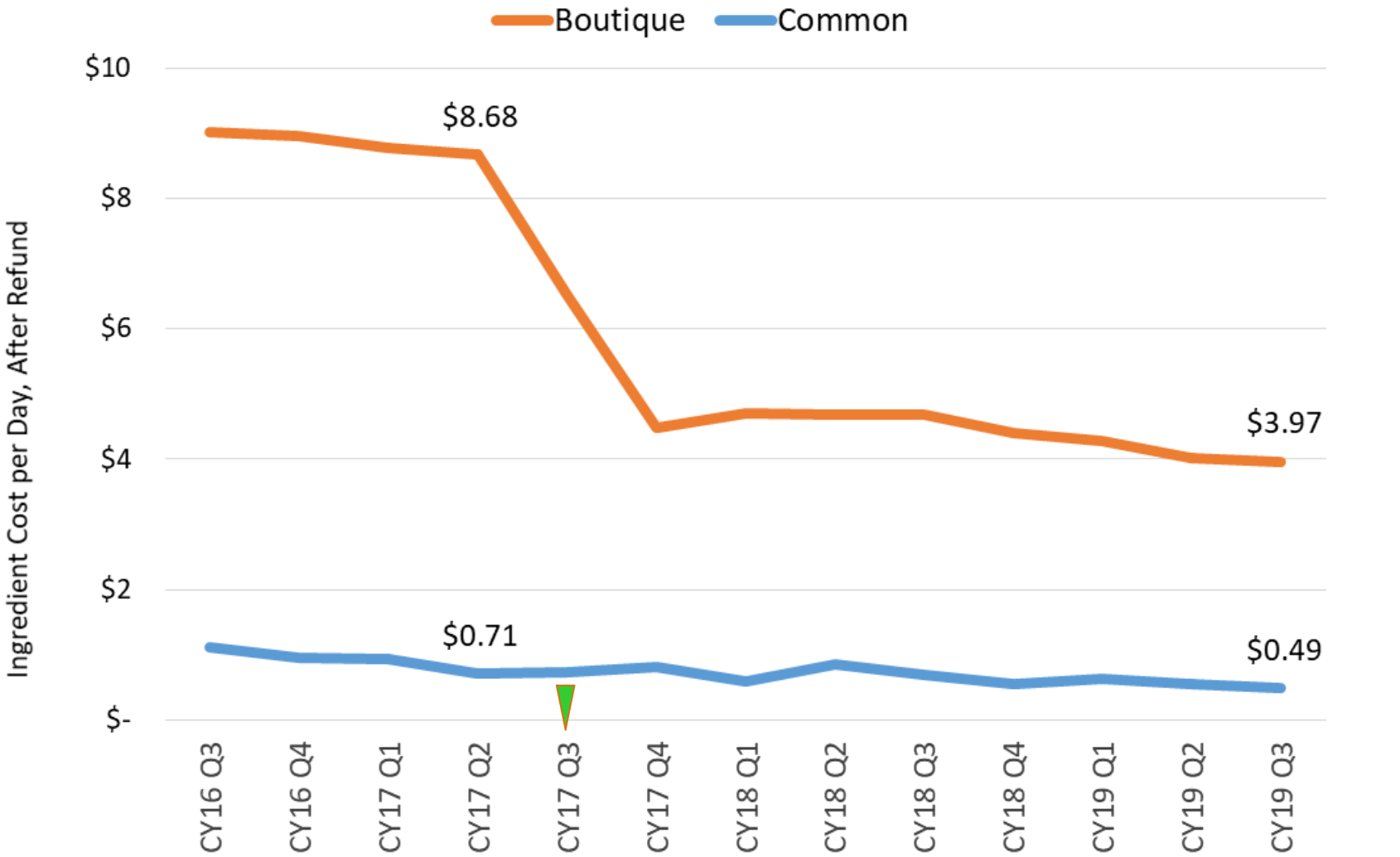
Tetracyclines
Net MHS Cost



Common
Boutique
$8,000,000
$6,000,000
$4,000,000
$2,000,000
$-
Net MHS Cost
$7.7M
$6.5M
$5.8M
$5.4M
$4.5M
$3.1M
$3.3M
$2.4M
$1.5M
$1.3M
Implementation Date
↓58%
↓83%
$43.3M per year
↓$28.4M/yr
$14.9M per year
CY15 Q3
CY15 Q4
CY16 Q1
CY16 Q2
CY16 Q3
CY16 Q4
CY17 Q1
CY17 Q2
CY17 Q3
CY17 Q4
CY18 Q1
CY18 Q2
CY18 Q3
CY18 Q4
CY19 Q1
CY19 Q2
CY19 Q3

Source: PDTS. Excludes patients with other health insurance.

Tetracyclines
Net MHS Cost per Day

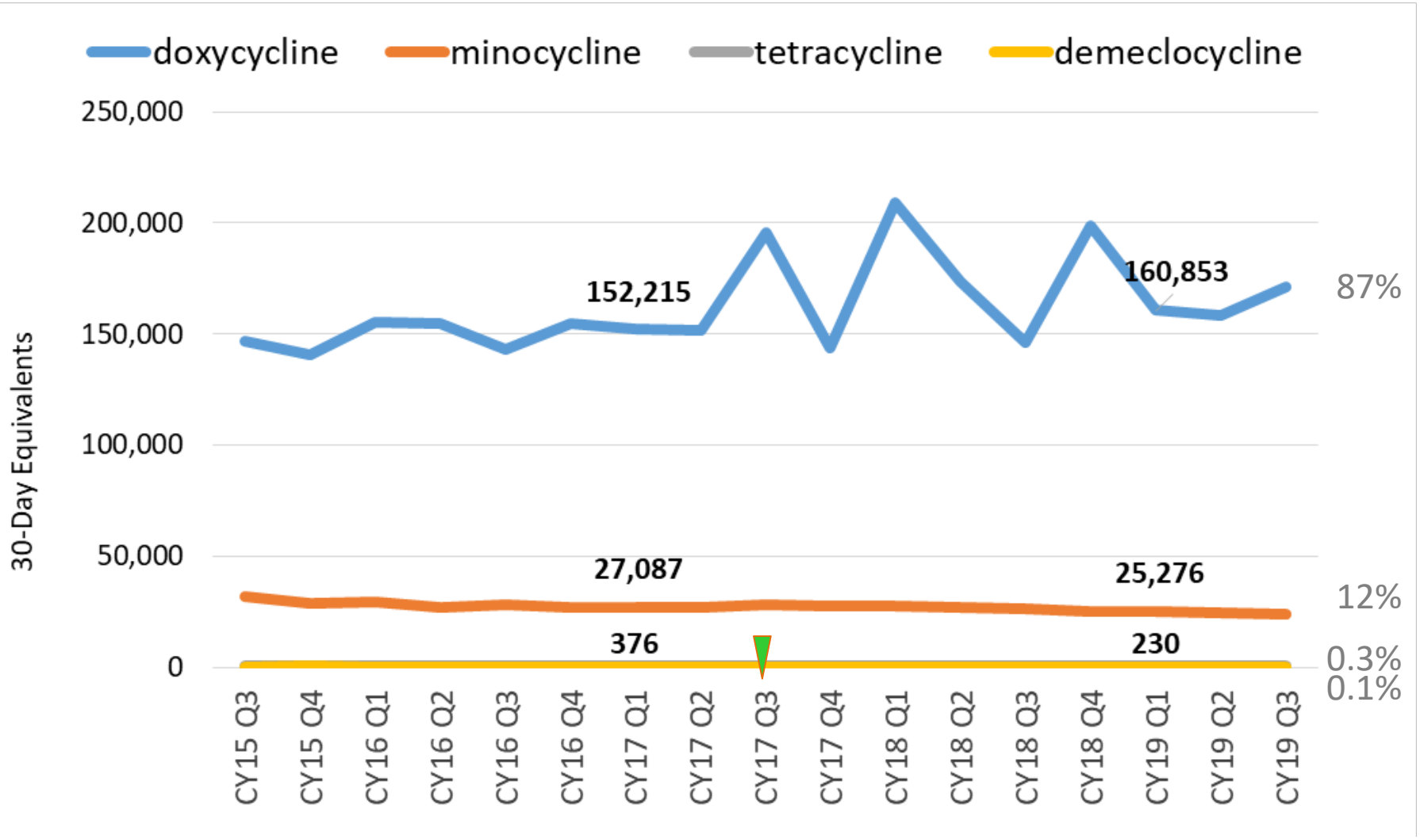


Source: PDTS. Excludes patients with other health insurance.

Drivers of Changes in Utilization and Cost

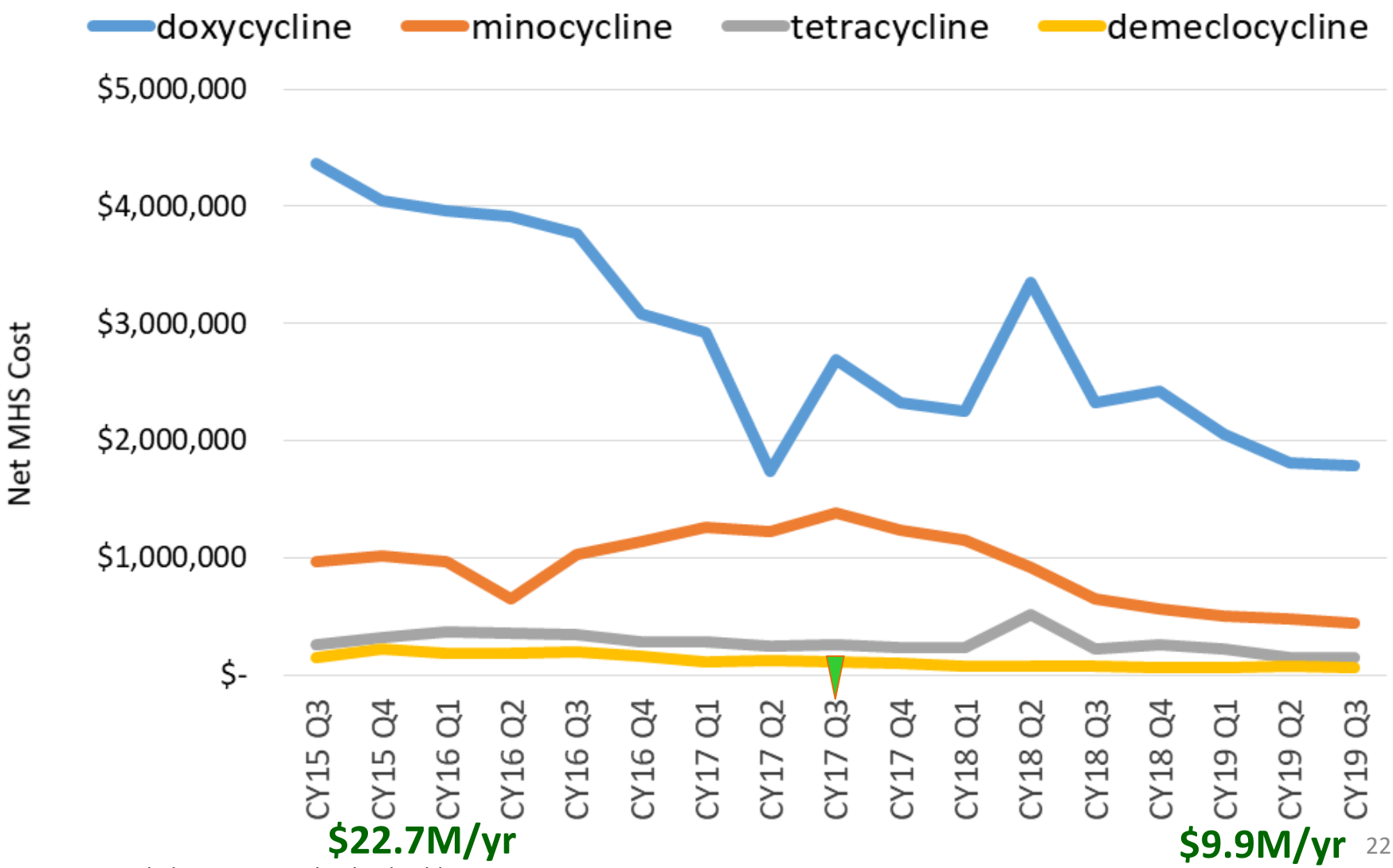
TCN Common Agents

TCN - Common Agents Utilization



Source: PDTS. Excludes patients with other health insurance.

TCN - Common Agents
Net MHS Cost

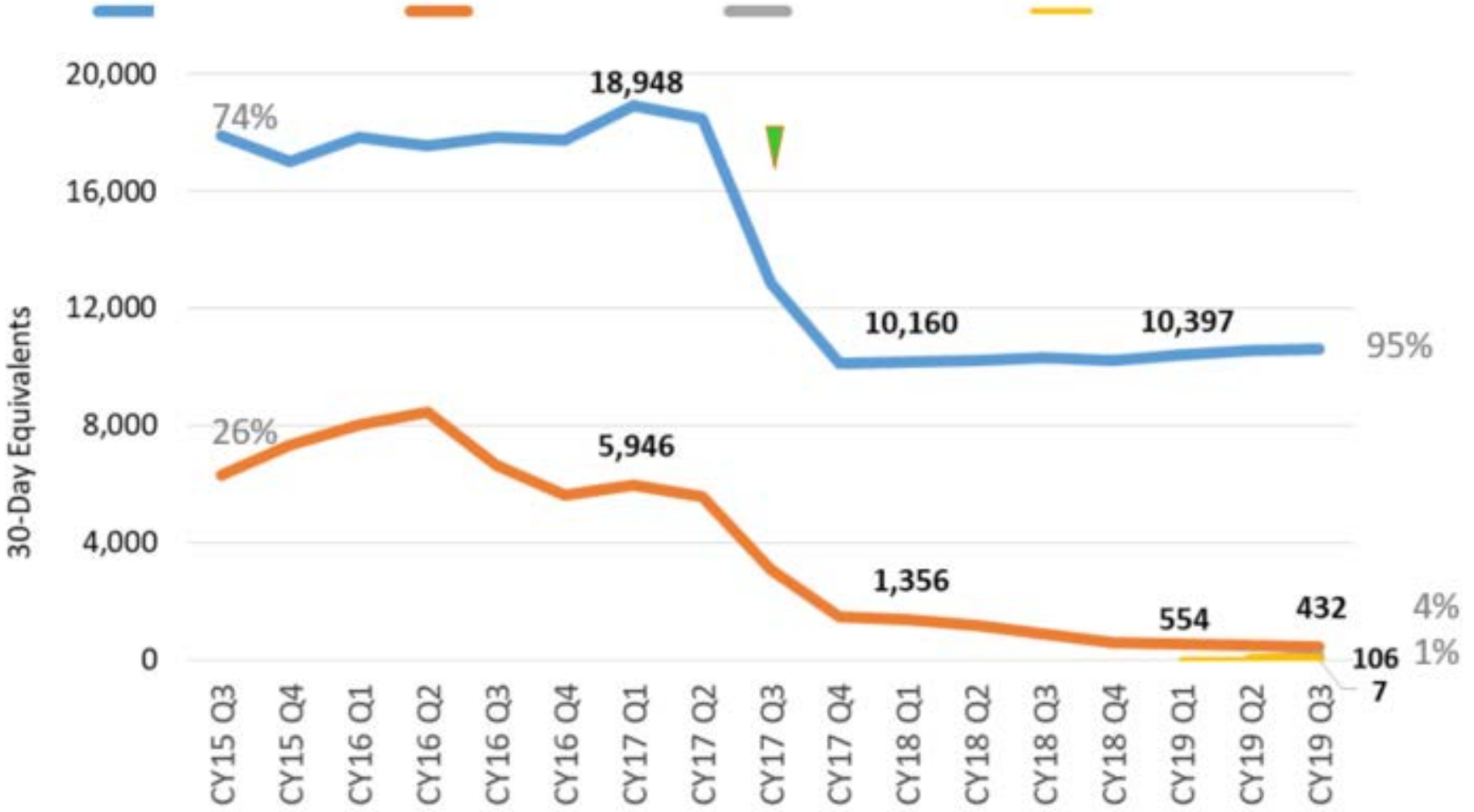


Source: PDTS. Excludes patients with other health insurance.

Drivers of Changes in Utilization and Cost

TCN Boutique Agents

TCN – Boutique Agents Utilization

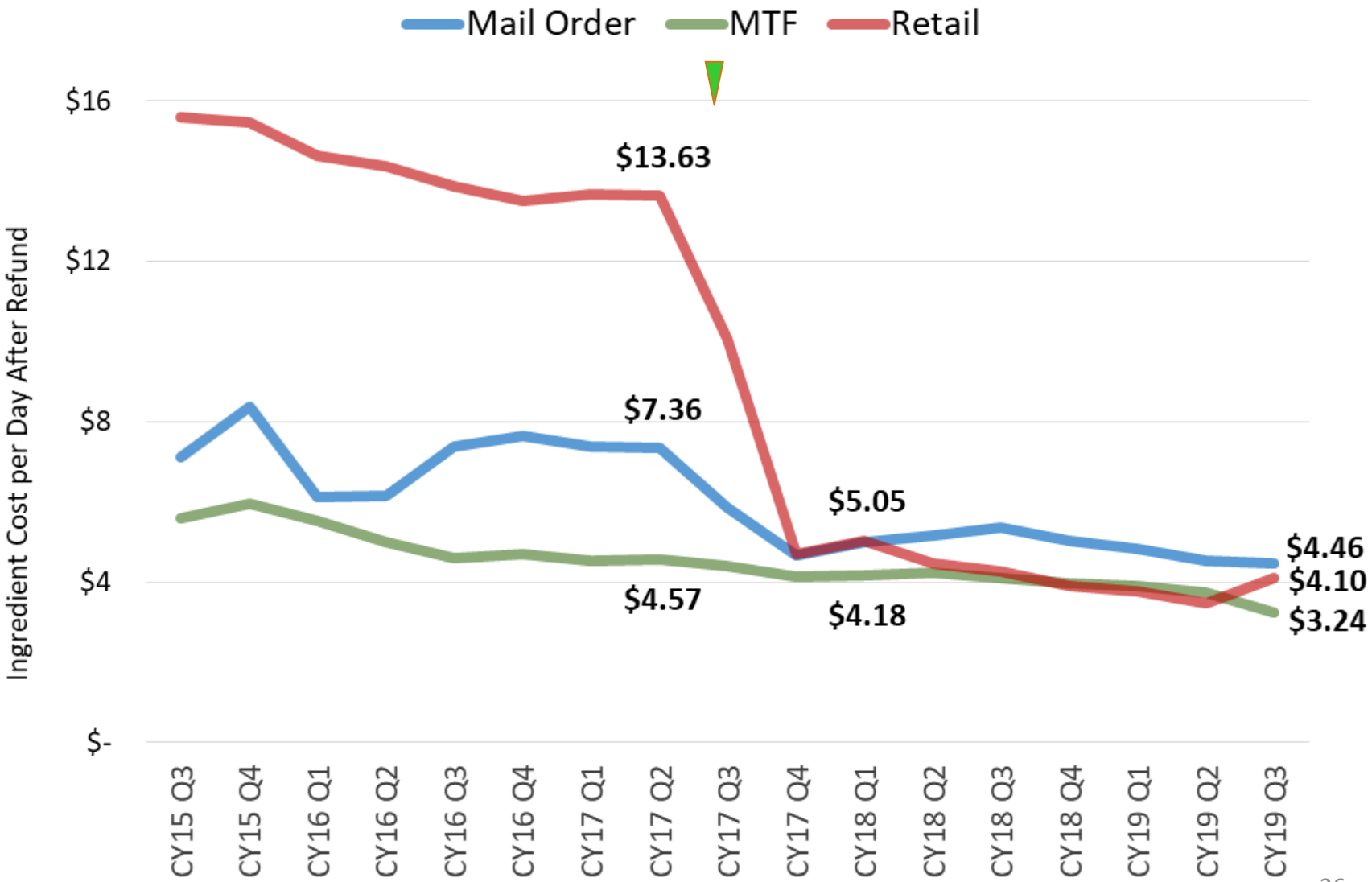


Source: PDTS. Excludes patients with other health insurance.

TCN – Boutique Agents
Net MHS Cost

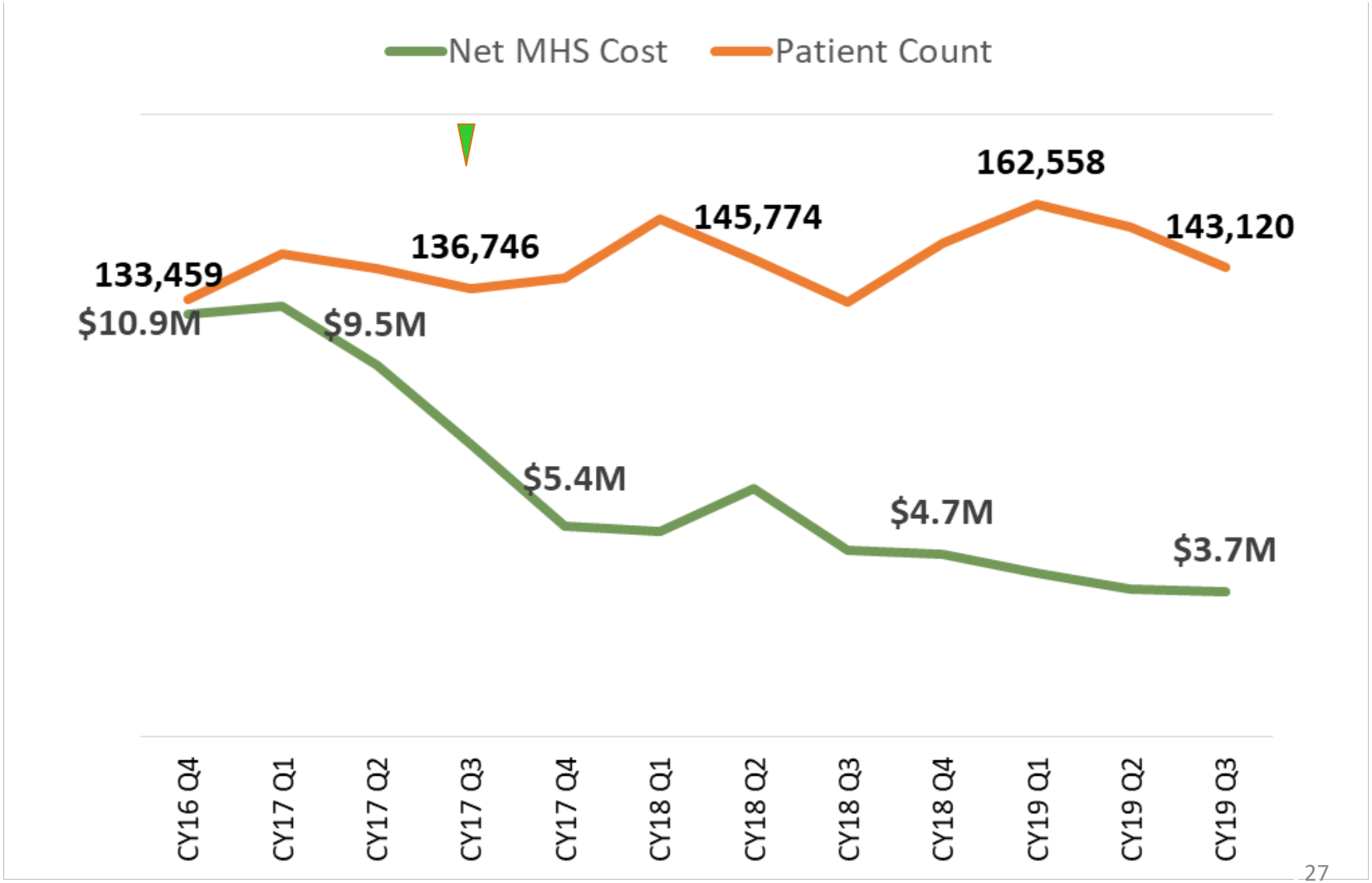
Source: PDTS. Excludes patients with other health insurance.

TCN – Boutique Agents (All)
Net MHS Cost per Day



Source: PDTS. Excludes patients with other health insurance.

Tetracyclines
Summary of Cost and Patient Count



Source: PDTS. Excludes patients with other health insurance.

Tetracycline UF Class Review Summary

- Tetracycline class review resulted in **significant and sustained cost avoidance** for the MHS
  - Post-implementation review shows that annual **cost avoidance exceeded the conservative BIA estimate**
- Utilization moved from more costly “boutique” agents to less costly “common” agents
- Also, within the “boutique” segment, market share **shifted from higher-cost to lower-cost agents**
- Patient count and total prescriptions were not negatively impacted from this UF class review