

Real-World Botulinum Toxin Utilization and Treatment Cost for Cervical Dystonia and Limb Spasticity among 15 Million Commercially Insured Members

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No external funding provided for this research

BACKGROUND

- Competition exists between the four botulinum toxin (BT) products: Onabotulinumtoxin A (ObA), Abobotulinumtoxin A (AbO), Incobotulinumtoxin A (InC), and Rimabotulinumtoxin B (RiM) for treating cervical dystonia (CD), limb spasticity (LS) and blepharospasm (BS).
- All four BT products are FDA-approved and guideline-supported for treating CD, three (ObA, AbO and InC) are approved for LS and two (ObA and InC) are approved for BS.^{1,2}
- BT product labeling information states every 12-week treatment frequency or longer for CD, LS and BS.^{2,3,4,5}
- Various studies have determined equivalent dosing units of 1:1 for InC to ObA, and nearly 3:1 for AbO to ObA.⁶
- Understanding CD, LS and BS real-world utilization, costs and dosing equivalents for the competing BTs will help inform insurers' BT category management strategies.

OBJECTIVE

Using 15 million commercially insured lives' integrated medical and pharmacy claims data, determine real-world BT treatment for CD, LS, and BS:

- Utilization and expenditure by product.
- BT product average claim cost, units per claim and days between claims.
- ObA equivalent units for AbO and InC for their respective FDA-approved indications.

METHODS

All analyses were conducted using administrative health care claims from 15 million commercially insured members.

Proportion of CD, LS and BS Use and Expenditure in the Botulinum Toxin Class

- Pharmacy and medical BT claims were queried from Jan. 1, 2018 to Dec. 31, 2018, using the Healthcare Common Procedure Coding System (HCPCS) codes (J0585, J0588, J0586, J0587) and Generic Product Identifier (GPI) codes (74400020052xx, 908900200021xx, 744000202021xx, 744000200321xx, 908900180021xx, 744000201020xx).
- Identified BT claims were assigned a CD, LS or BS diagnosis based on the International Classification of Diseases (ICD-10) diagnosis code on the medical claim. For the 3% of BT claims processed through the pharmacy benefit, BT utilization diagnosis was assigned via a look back at the members' medical claims.
- All BT claims for the same member that occurred on the same date of service were summed to account for vial wastage.
- The BT claims, units, and expenditures were then summed by indication.
- All costs were total paid amount inclusive of plan plus member paid, and per member per month (PMPM) calculations were made using monthly total membership.

Average BT Product Claim Cost, Units per Claim and Average Days Between BT Product Claims by Indication

- The average BT product claim cost and units per claim were calculated for each indication of CD, LS and BS.
- At the BT product level, all claims for each indication were aggregated. Next, using BT product claims by indication at the member level, the days between each BT product were identified. The member-level days between each BT product by indication claim was then averaged to create an average-days measure between BT product claims by indication.

Calculated Real-World Equivalent Units for Botulinum Toxin Products by Indication

- Separate analyses for each of the ObA, AbO and InC products were conducted to calculate the average units per claim by indication.
- Equivalent units were calculated using the average units per claim for InC divided by the average units per claim for ObA for their same respective FDA-approved indications. This process was repeated for AbO.

RESULTS

Proportion of CD, LS and BS Use and Expenditure in the Botulinum Toxin Class (Figures 1, 2)

- Among 15 million commercially insured members from Jan. 2018 to Dec. 2018 (12 months), a total of 58,199 BT claims were identified, resulting in a total spend of \$76.4 million.
- 96.4% (56,087 of 58,199) of claims and 96.6% (\$73.8 million of \$76.4 million) of spend were medical claims.
- LS accounted for 14.2% (8,244 of 58,199) of claims and 21.3% (\$16.3 million of \$76.4 million) of all BT spend.
- CD accounted for 8.0% (4,628 of 58,199) of claims and 9.7% (\$7.4 million of \$76.4 million) of spend.
- BS accounted for 3.3% (1,913 of 58,199) of claims and 1.3% (\$1.0 million of \$76.4 million) of spend.
- Migraine accounted for 61.8% (35,970 of 58,199) of claims and 59.7% (\$45.6 million of \$76.4 million) of spend.
- Other accounted for 12.8% (7,444 of 58,199) of claims and 8.0% (\$6.1 million of \$76.4 million) of spend.

Average BT Product Claim Cost, Units per Claim and Average Days Between BT Product Claims by Indication (Table 1)

- ObA had the highest average claim cost for all three indications (LS, CD and BS) compared to the other BTs.
- InC had the lowest average claim cost for LS and BS, which was 26% and 29% lower than ObA, respectively.
- Shifting all ObA for LS (\$15.0 million) to InC (26% savings) would result in ~\$3.9 million in annual savings.
- Shifting all ObA for BS (\$0.9 million) to InC (29% savings) would result in ~\$0.3 million in annual savings.
- AbO had the lowest average claim cost for CD, which was 33% lower than ObA.
- Shifting all ObA for CD (\$6.5 million) to AbO (33% savings) would result in ~\$2.1 million in annual savings.
- Days between claims for the different BTs across the three indications (CD, LS and BS) were not substantially different from one another.

Calculated Real-World Equivalent Units for Botulinum Toxin Products by Indication (Table 2)

- The calculated equivalent units for InC to ObA was found to be 1:1, 0.9:1 and 0.8:1 for CD, LS and BS, respectively.
- The calculated equivalent units for AbO to ObA was found to be 2.9:1 and 2.8:1 for CD and LS, respectively.

FIGURE 1

Botulinum Toxin Class Utilization and Cost by Diagnosis in a Commercially Insured Population of 15 Million Members

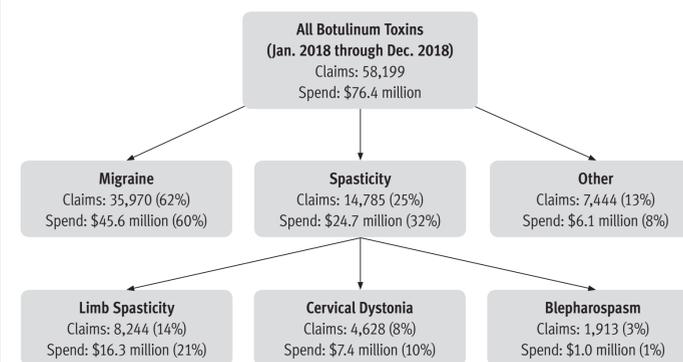


TABLE 1

Botulinum Toxin Average Claim Cost, Days Between Claims and Extrapolated Annual Treatment Cost per Treated Patient for Cervical Dystonia, Limb Spasticity and Blepharospasm

Botulinum toxin	Number of claims	Average cost per claim	Average days between claims	Calculated average claims per year per treated patient [†]	Calculated annual treatment cost per treated patient*
Cervical Dystonia					
Botox® (Onabotulinumtoxin A)	3,986	\$1,633	106	3.4	\$5,552
Xeomin® (Incobotulinumtoxin A)	401	\$1,374	103	3.5	\$4,809
Dysport® (Abobotulinumtoxin A)	126	\$1,099	105	3.5	\$3,847
Myobloc® (Rimabotulinumtoxin B)	115	\$1,518	105	3.5	\$5,313
Limb Spasticity					
Botox® (Onabotulinumtoxin A)	7,425	\$2,022	110	3.3	\$6,673
Xeomin® (Incobotulinumtoxin A)	354	\$1,497	110	3.3	\$4,940
Dysport® (Abobotulinumtoxin A)	380	\$1,582	125	2.9	\$4,588
Blepharospasm					
Botox® (Onabotulinumtoxin A)	1,668	\$556	113	3.2	\$1,779
Xeomin® (Incobotulinumtoxin A)	235	\$392	112	3.3	\$1,294

Claims were identified using integrated pharmacy and medical claims from approximately 15 million commercially insured members from Jan. 2018 to Dec. 2018. *Calculated annual cost = Average Cost per Claim x Calculated Claims per Year. †Calculated by dividing 365 days (1 year) by the average days between claims.

TABLE 2

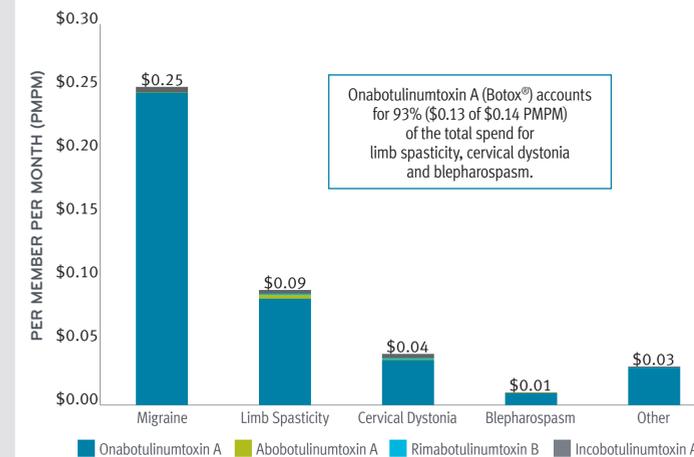
Botulinum Toxin A and Onabotulinumtoxin A (ObA) Equivalent Unit Comparison

Botulinum toxin	ObA literature equivalent unit(s) [§]	ObA equivalent unit price*	Prime Therapeutics real-world data (average units per claim) [†]			ObA equivalent unit(s) based on Prime Therapeutics real-world data [†]		
			LS	CD	BS	LS	CD	BS
Botox® (Onabotulinumtoxin A)	N/A	\$5.78	256	229	83	-	-	-
Dysport® (Abobotulinumtoxin A)	3	\$4.76	718	662	-	2.8	2.9	-
Xeomin® (Incobotulinumtoxin A)	1	\$4.77	228	228	68	0.9	1	0.8

LS = Limb Spasticity; CD = Cervical Dystonia; BS = Blepharospasm. ObA = Onabotulinumtoxin A. *Price based on Average Sales Price from R1 Health; accessed Aug. 2, 2019, and converted to ObA equivalent units based on literature. † Botulinum toxin claims were identified using integrated pharmacy and medical claims from approximately 15 million commercially insured members from Jan. 2018 to Dec. 2018.

FIGURE 2

Botulinum Toxin Cost Per Member Per Month (PMPM) by Indication Among 15 Million Commercially Insured Members in 2018



Botulinum toxin claims were identified using integrated pharmacy and medical claims from approximately 15 million commercially insured members from Jan. 2018 to Dec. 2018. Diagnosis was assigned using the diagnosis found on the botulinum toxin claim. Total allowed amount, plan paid plus member paid was used.

CONCLUSIONS

- This real-world study of 15 million commercially insured members using integrated medical and pharmacy data found that limb spasticity (LS), cervical dystonia (CD), and blepharospasm (BS) accounted for one-quarter of all botulinum toxin (BT) claims and one-third of all expenditures (\$0.14 PMPM of the total \$0.42 PMPM).
- For BT used to treat LS, CD, and BS, the ObA product (Botox®) accounts for 93% of expenditures (\$0.13 PMPM) and has the highest average claim cost for all three indications.
- Average days between claims was nearly identical indicating that formulary-prefering AbO (Dysport®) or InC (Xeomin®) instead of ObA (Botox®) would not increase claim frequency for these three indications.
- Calculated real-world equivalent units for each indication match closely with equivalent units found in medical literature.⁶
- Shifting all ObA (Botox®) use to the lowest cost BT for each indication would result in an estimated savings of ~\$6.3 million (\$0.04 PMPM) annually in this 15-million-member commercially-insured population.
- This real-world BT integrated medical and pharmacy claims data research establishes confidence in BT product conversion savings estimates for treating cervical dystonia, limb spasticity and blepharospasm.

LIMITATIONS

- Administrative pharmacy and medical claims have the potential to be miscoded and include assumptions of members' actual drug use and diagnoses.
- BT products indicated for spasticity are approved based on location of spasticity (upper or lower) which are rarely differentiated by the ICD-10 codes found on medical claims.
- Number of muscles being injected per claim cannot be determined using administrative claims data which can impact the number of units and cost per claim.
- Claim costs were not adjusted for site of care (e.g., facility, professional or pharmacy) which can contribute to differing cost markups on BT claims.
- The data used in this study was limited to a commercial population and results are not generalizable to Medicare or Medicaid populations.

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