OnabotulinumToxinA (Botox®) and Migraine: Persistence, Utilization and Expenditure within the Botulinum Toxin Drug Class

PRIME THERAPEUTICS®

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Background

- There are currently four FDA-approved botulinum toxin (BT) products: onabotulinumtoxinA (ObA), incobotulinumtoxinA, abobotulinumtoxinA, and rimabotulinumtoxinB.
- They are approved for unique (e.g. chronic migraine prevention and gland secretion) and overlapping (e.g. muscle spasticity and dystonia) indications.
- ObA is the only FDA-approved BT for chronic migraine prevention and was the only biologic migraine treatment from its approval in 2010 until 2018, when calcitonin gene-related peptide (cGRP) products were approved for chronic and episodic migraines.[1,2]
- ObA must be administered by a health care provider and each administration consists of 155 units (of a 200-unit vial) divided across 31 injections sites around the face, head, and neck every 12 weeks.[3,4]
- In 2018, cGRP products were launched, representing the first biologic competitor to ObA for chronic migraine prevention.
- New biologic competition in the chronic migraine category highlights the importance for insurers to understand real-world migraine ObA use, cost, and persistency to inform future management strategies.

Objectives

- Determine in the real world:
  - Proportion of BT utilization and expenditure that were migraine ObA by utilizing integrated medical and pharmacy claims data.
  - Average annual migraine ObA therapy cost inclusive of drug, drug waste, and drug administration.
  - Migraine ObA treatment persistence over one year for members new to therapy.
  - 12-month pre- and post-migraine cost of care for members newly initiating migraine ObA therapy.

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Methods

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

Proportion of Migraine ObA Use and Expenditure in the Botulinum Toxin Class

- Integrated medical and pharmacy claims data were queried for all BT claims based on the Healthcare Common Procedure Coding System (HCPCS) codes for BTs (J0585, J0588, J0586, J0587) and Generic Product Identifier (GPI) codes for BTs (74400020xx, 90890020xx, 90890018xx) from Oct. 1, 2017 to Sept. 30, 2018.
- Identified BT claims were assigned a migraine diagnosis based on medical claim ICD-10 diagnosis codes (chronic migraine G43.709, G43.719, G43.701 or G43.711, or other migraine G43.xx).
- All BT claims for the same member that occurred on the same date of service were summed to account for vial wastage and defined a unique BT claim.
- Descriptive statistics were used to present the ObA portion of all BT claims and expenditure.
- All costs were total allowed amount inclusive of plan plus member paid, and per member per month (PMPM) calculations were made using monthly total membership.

Average Annual Cost of Migraine ObA Therapy

- The average cost per claim for migraine ObA was calculated from claims identified in the previous analysis.
- To determine the administration cost, the Current Procedural Terminology (CPT) code (64615) for chemodenervation associated with administration of migraine ObA, which occurred on the same date as a migraine ObA claim, was identified and the average cost was calculated. The cost of an office visit was not included.
- The average annual cost for migraine ObA therapy inclusive of administration cost was calculated based on four administrations per year according to the FDA-label.[4]

New Start Migraine ObA Persistence and Total Migraine Cost of Care

- Members were identified as having a claim for migraine ObA from Oct. 1, 2016 through Sept. 30, 2017.
- Members were required to have one year of continuous enrollment prior to, and one year after, the ObA claim.
- Members new to ObA therapy were defined as members with no migraine ObA claim one year prior to their identified ObA claim.
- Number of ObA claims for migraine were then totaled for each member during the one-year follow-up period.
- Persistent members were defined as having four or more total migraine ObA claims, including the initial claim, and non-persistent members were defined as having three or less claims during the one-year follow-up period.
- Total pharmacy and medical claim allowed costs including member and plan paid were totaled for members new to migraine ObA therapy for one year prior to, and one year after starting ObA treatment.
- Medical costs were determined to be migraine related if the medical claim included a migraine diagnosis (G43.xx) in the primary position.
- Pharmacy claims were determined to be migraine related if they were in one of the following drug classes: ergot, opioid, triptan, beta-blocker, antidepressant, or anticonvulsant.

Results

Proportion of Migraine ObA Use and Spend in the Botulinum Toxin Class (Figures 1 and 2)

- Among 15 million commercially insured members from Oct. 2017 through Sept. 2018 (12 months), a total of 61,944 BT claims were identified, resulting in a total spend of $80.3 million.
- ObA accounted for 96 percent (59,157 of 61,944) of claims and 96 percent ($77.1 million of $80.3 million) of spend.
- ObA for migraine resulted in 66 percent (40,694 of 61,944) of all BT claims and 65 percent ($52.3million of $80.3 million) of spend.
- Average quarterly PMPM for migraine ObA was $0.28 (65 percent) of the $0.43 PMPM for the entire BT category.

Average Annual Cost of Migraine ObA Therapy (Figure 4)

- $6,304 was the average annual cost for migraine ObA therapy for an adherent member inclusive of drug, drug waste and drug administration, assuming four ObA treatments annually.
- $1,286 average cost per claim for migraine ObA (average $6.63 per unit multiplied by average 194 units per claim).
- $290 average cost per ObA migraine administration ($11.8 million in administration costs divided by 40,694 migraine ObA treatments).

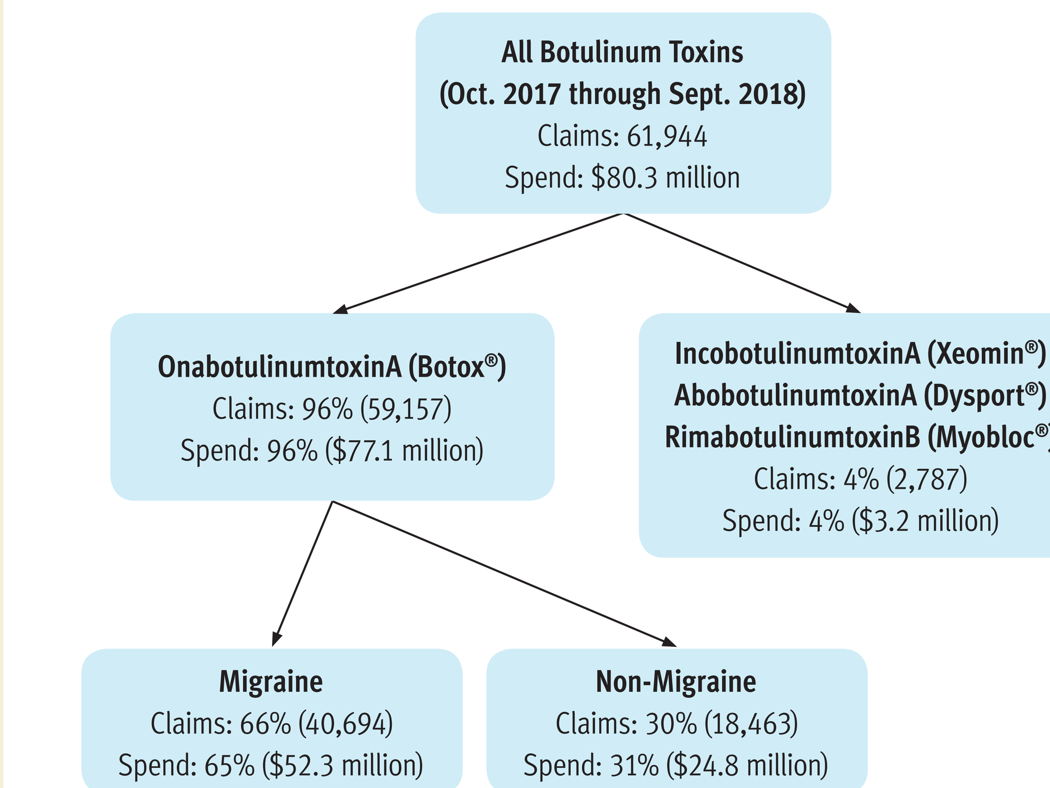
New Start Migraine ObA Persistence and Total Migraine Cost of Care (Figures 3 and 4)

- A total of 12,326 members were identified as having a migraine ObA claim during the 12-month identification period, Oct. 2016 through Sept. 2017.
- 48 percent (5,964 of 12,326) of the members met the continuous enrollment requirement, and 41 percent (2,473 of 5,964) were identified as being new to migraine ObA therapy.
- Of the 2,473 members who received their initial dose of ObA, 18 percent (454), 18 percent (447), and 17 percent (417) did not receive their second, third and fourth doses respectively, and only 47 percent of new starts received four or more doses during the one-year period.
- $2,467 average total migraine costs for ObA new starts one year prior to ObA treatment, with $760 in migraine medical costs and $1,707 in migraine pharmacy costs.
- $7,422 average total migraine costs for ObA new starts one-year post ObA treatment, with $851 in migraine medical costs, $1,754 in migraine pharmacy costs, and $4,817 in migraine ObA and ObA administration costs.
- Migraine ObA, ObA waste and ObA administration accounted for 65 percent of all migraine costs in one-year post treatment period.
- ObA therapy was associated with a three-fold increase in migraine total cost of care in the year post ObA initiation compared to the prior year.

Limitations

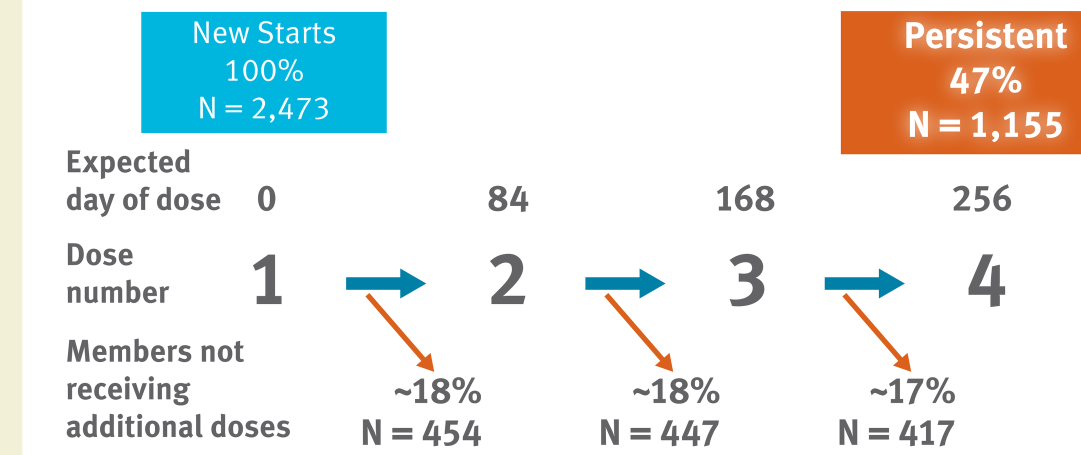
- Administrative pharmacy and medical claims have the potential to be miscoded and include assumptions of members' actual drug use and diagnoses.
- ObA is only FDA-approved for chronic migraine and therefore members identified as using it for "other migraine" may not have had their diagnosis coded appropriately.
- The data used in this study was limited to a commercial population and results are not generalizable to Medicare or Medicaid populations.
- Several different methods for determining persistence exist. This analysis used four or more claims in a one-year period to determine persistence, and other methods may generate different results. Patients may find fewer annual doses effectively prevent migraines.
- This analysis only included migraine total cost of care from a payer perspective and does not address ObA's impact to societal costs such as missed work days.

Figure 1. Botulinum Toxin Class Utilization and Spend by Migraine Diagnosis in a Commercially Insured Population of ~15 Million



Botulinum Toxin claims were identified using integrated pharmacy and medical claims from approximately 15 million commercially insured members from Oct. 2017 through Sept. 2018. Migraine diagnosis was assigned to claims based on medical claim diagnosis (G43.xx). Total allowed amount was used to determine spend (plan paid plus member paid).

Figure 3. OnabotulinumtoxinA (Botox®) Treatment Persistency Among 2,473 New Migraine Treatment Initiators.

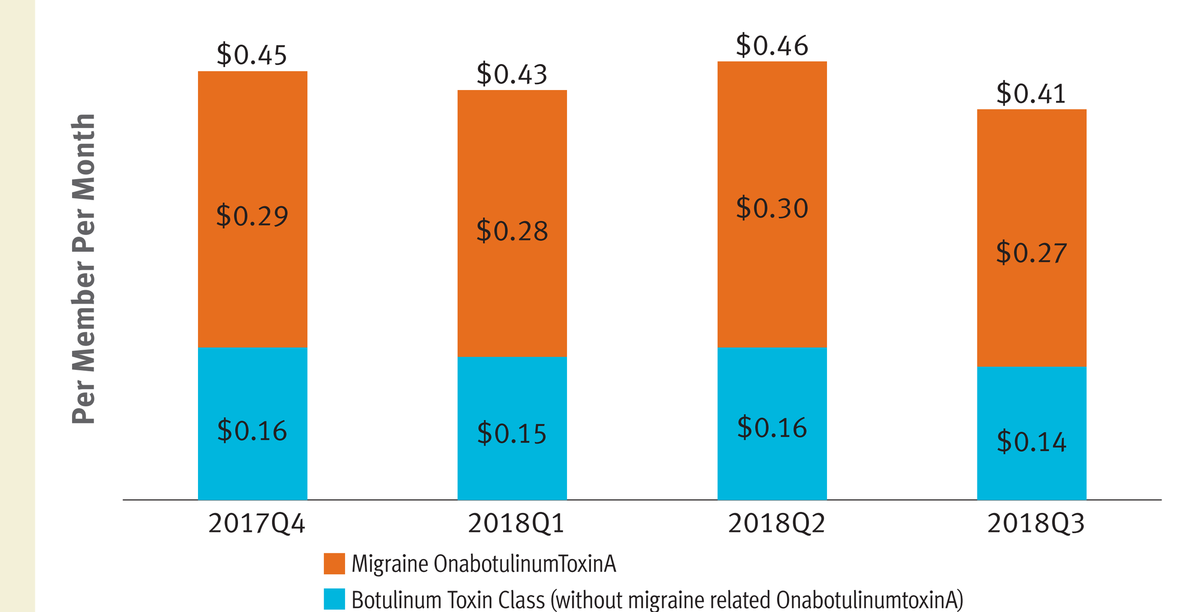


Members were identified as having a claim for ObA for migraine from Oct. 1, 2016 through Sept. 30, 2017. Members required one year of continuous enrollment prior to and one year after the claim. New starts were defined as members who did not have a ObA claim during the one year prior to their identified ObA claim.

Conclusions

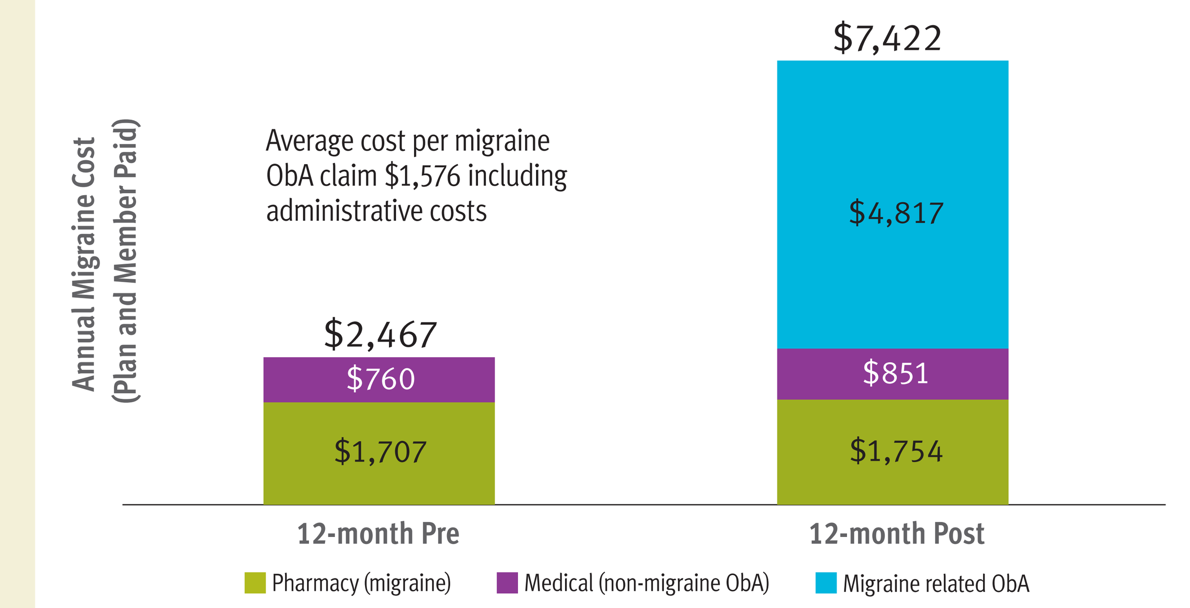
- ObA migraine treatment accounted for 65 percent ($0.28 PMPM) of the total $0.43 PMPM botulinum toxin spend and the vast majority of botulinum toxin spend came through the medical benefit, in this real-world study of 15 million commercially insured members.
- Actual medical claim total paid for ObA migraine annual treatment was found to be $6,304, with drug waste and provider administration accounting for 34 percent of the cost.
- Only 47 percent of members new to ObA migraine therapy were persistent to their ObA therapy, during a year of follow up.
- ObA migraine treatment did not reduce migraine medical or pharmacy costs and contributed to a three-fold increase in migraine costs after starting ObA treatment.
- ObA migraine therapy real-world utilization and costs should be used to inform managed care pharmacy decisions in the botulinum toxin class and when comparing ObA to the cGRP drug class for treating chronic migraine.

Figure 2. Botulinum Toxin Class Per Member Per Month (PMPM): Migraine OnabotulinumtoxinA (Botox®) vs Others



Botulinum Toxin claims were identified using integrated pharmacy and medical claims from approximately 15 million commercially insured members from Oct. 2017 through Sept. 2018. Migraine diagnosis was assigned to claims based on medical claim diagnosis (G43.xx). Total allowed amount (plan paid plus member paid) was summed and the PMPM was calculated for each quarter.

Figure 4. 12-Month Pre- and Post-Migraine Cost of Care for Members Newly Initiating Migraine OnabotulinumtoxinA (Botox®) Therapy



Members were identified by a migraine ObA claim from Oct. 2016 through Sept. 2017. Continuous enrollment was required one year prior to, and one year after the ObA claim. New starts were defined as no previous ObA use in the previous year. Pharmacy and medical costs are inclusive of both member and plan paid costs. Pharmacy (migraine) was inclusive of costs for all opioids, ergotamines, triptans, betablockers, anticonvulsants, and antidepressants. Medical (non-ObA migraine) includes any medical claim with a primary diagnosis of migraine that does not include migraine ObA or migraine ObA administration costs.

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