

## PEYRONIE'S DISEASE

# Cost of Intralesional Collagenase Clostridium Histiolyticum Therapy Versus Surgery for the Management of Peyronie's Disease: A Claims-Based Analysis (2009–2019)



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## ABSTRACT

**Background:** Collagenase Clostridium histolyticum (CCH), which was approved by the FDA for the treatment of Peyronie's disease (PD) in 2013, may obviate the need for surgery but its historically high cost must be considered when offering CCH vs surgical intervention to affected patients.

**Aim:** To compare trends of intralesional injections vs surgical treatment for PD and assess the contemporary cost of treatment with CCH vs surgical intervention.

**Methods:** We reviewed 2009–2019 MarketScan Commercial Claims data to identify all men 18 years and older with PD. CPT and HCPCS codes were used to identify PD treatments for each patient. Associated insurance claims in USD were summed for each treatment type.

**Outcomes:** Total and out-of-pocket costs, as well as frequencies, for treatments were calculated on a yearly basis and the Cochran-Armitage test was used to compare frequencies before and after FDA approval of CCH.

**Results:** Of 89,205 men diagnosed with PD, 21,605 (24.2%) underwent treatment; most required only intralesional injections, however 1,519 (7.0%) received only surgical therapy and 1,951 (9.0%) required medical and surgical therapy. Intralesional CCH use sharply increased after its FDA-approval in 2013 with a concomitant fall of intralesional verapamil use. The use of both surgical plication and plaque grafting decreased steadily from 2009 to 2019. The median cost per patient for all 3 treatments increased over the study time-period: \$1,856 to \$3,196 for plication, \$2,233 to \$3,631 for plaque grafting, and \$6,940 to \$8,895 per cycle for CCH. Out-of-pocket median patient contribution for plication, plaque grafting, and per cycle intralesional CCH injection were similar over the study period and never exceeded \$300.

**Clinical Implications:** CCH is significantly more expensive than any surgical treatment option, however, the out-of-pocket patient contribution for surgery and CCH are similar.

**Strengths & Limitations:** This study incorporated all procedure costs and is the most contemporary, comprehensive, and accurate reflection of overall and out-of-pocket costs to patients for surgical and intralesional PD therapies. We anticipate these data to allow for a more complete discussion between patients and providers regarding their care. The use of a commercial claims database prohibited assessment of post-procedural costs and treatment outcomes.

**Conclusion:** CCH use has increased significantly since its FDA approval in 2013 with out-of-pocket patient contribution comparable to surgical therapy despite significantly higher total treatment costs. **Walton EL, Quinn TP, Mulloy E, et al. Cost of Intralesional Collagenase Clostridium Histiolyticum Therapy Versus Surgery for the Management of Peyronie's Disease: A Claims-Based Analysis (2009–2019). Sex Med 2022;10:100517.**

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**Key Words:** Peyronie's Disease; Cost Analysis; Intralesional Collagenase; Surgical Plication; Plaque Grafting

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## INTRODUCTION

Peyronie's disease (PD) is a debilitating progressive fibrotic disorder of the tunica albuginea of the corpora cavernosa with variable prevalence in the United States.<sup>1</sup> PD is associated with significant sexual and psychological morbidity, manifesting in decreased sexual performance and patient self-confidence.<sup>2–4</sup> Fortunately, multiple treatment options are available, including oral medication, injectable therapy, and complex surgical reconstruction. Recent trends in management strategies show that most urologists favor conservative treatment, and intralesional injections account for 82% of all procedures performed for PD.<sup>5</sup> Intralesional therapies include interferon, verapamil, and collagenase *Clostridium histolyticum* (CCH; Xiaflex, Endo Pharmaceuticals, Malvern, PA, USA), which was approved by the Federal Drug Administration (FDA) in December 2013. CCH treatment is associated with improvement in both penile curvature and sexual function.<sup>6,7</sup> As such, CCH may obviate the need for surgical intervention for many men with PD. However, the cost of CCH remains high, and must be considered when evaluating the benefit of CCH vs surgical intervention for affected patients.

This study aimed to assess the comparative contemporary cost of treatment with CCH vs surgical intervention, as well as answer the following question: did the distribution of Peyronie's disease treatments change after the FDA approval of CCH?

## MATERIALS AND METHODS

We used the MarketScan Commercial Claims and Encounters database to identify all men >18 years of age who underwent evaluation and/or treatment for diagnosis of PD between 2009 and 2019, using the International Classification of Disease (ICD) diagnostic codes (ICD-10 [N 48.6] and ICD-9 [607.85]). The MarketScan database comprises information from over 350 private sector US based health plans for more than 200 million patients. All enrolled individuals are assigned deidentified patient numbers and are followed longitudinally over time. We abstracted information on age, medical comorbidities, treatment types, Charlson Comorbidity Index, obesity, insurance plan, employment status and geographic setting for the study cohort.

Treatments were identified using Current Procedural Terminology (CPT) and Healthcare Common Procedure Coding System (HCPCS) codes (Appendix 1) for penile intralesional injection (with verapamil, interferon alpha 2B, or CCH), penile plication, and penile plaque incision/excision with grafting, and insertion of penile prosthesis (IPP). Prescription therapies were identified through outpatient records and by J-codes specific to injection drug type. Each code has an associated insurance claim with a specific amount billed in USD for the procedure performed or material used; claims include the amount paid by the commercial insurance provider and the amount paid by the

patient. The total cost of each treatment was calculated by summing the claim amounts for the codes specified in Appendix 1. Surgical costs included professional, facility, and anesthesia fees. Intralesional injection therapy included procedure fees and medication cost. We elected to present the median patient-level cost per treatment.

Two assumptions regarding CCH treatment were made for cost analysis: one HCPCS code reflected 2 injections and was analyzed as one treatment cycle (per manufacturer recommendation); and any repeat CCH injections within a 10-day period were analyzed as a single treatment cycle. Patients who received only oral therapies (including oral verapamil) were excluded from this analysis. To minimize confounding, we also excluded procedure codes for insertion or revision of malleable or inflatable penile prostheses when a concomitant diagnosis of erectile dysfunction (ED) was noted.

We assessed trends in treatment type on a year-by-year basis and used the Cochran-Armitage test of trend to compare the frequency of medical and surgical therapies for PD before and after January 1, 2014. Generalized chi-square test was used for categorical variables and Wilcoxon rank-sum test for continuous covariates. All analyses were completed using SAS software version 9.4 (SAS Institute Inc, Cary, NC). Significance was set at an alpha value of .05. This analysis was deemed IRB exempt on the basis of research using completely deidentified data.

## RESULTS

A total of 89,205 men were diagnosed with PD from 2009 to 2019. Cohort characteristics are displayed in Table 1. Half of men were within the age group of 48–60 years. Diabetes mellitus affected 16.8% of men. ED impacted 46.7% of men; it was present prior to PD diagnosis in 38.4% of the cohort. 21,605 (24.2%) men from the cohort underwent PD treatment. Table 2 summarizes the treatments administered during the study period. Most patients only received medical therapy, however, 1,519 (7.0%) received surgery alone and 1,951 (9.0%) required both medical and surgical therapy. Within the combination subgroup, 73% received medical therapy prior to any surgical therapy.

Figure 1 depicts year-to-year trends in the annual use of intralesional injection and surgical therapies for PD. The annual use of CCH injections increased sharply after FDA approval and continued to rise from 2014 to 2019 (51.1% vs 60.6% of all therapies,  $P < .0001$ ). Concurrently, annual verapamil injection use dropped sharply from 2013 to 2014, and this decline continued through 2019 (81.4% vs 37.0% vs 25.7% of all therapies,  $P$  value  $< .0001$ ). Very few patients (less than 1% at each time point) received intralesional injection with interferon alpha-2b. Among surgical patients, plication was more common than plaque grafting; 15.5% required both procedures. The annual use of both surgical plication (12.8% vs 9.1% of all therapies,  $P < .0001$ ) and plaque grafting (9.4% vs 4.5% of all therapies,  $P <$

**Table 1.** Demographic characteristics of the analytical cohort

Covariate	Total (N = 89,205)
Age at PD diagnosis*	52.4 ± 9.7
18–48	21,156 (23.7)
48–60	45,211 (50.7)
60+	22,838 (25.6)
Year of PD diagnosis	
2009	11,912 (13.4)
2010	9,357 (10.5)
2011	10,154 (11.4)
2012	9,972 (11.2)
2013	7,796 (8.7)
2014	9,321 (10.4)
2015	5,442 (6.1)
2016	6,004 (6.7)
2017	5,644 (6.3)
2018	6,839 (7.7)
2019	6,764 (7.6)
Charlson Comorbidity Index	
0	52,820 (59.2)
1	16,975 (19)
2	8,634 (9.7)
3+	10,776 (12.1)
Diabetes mellitus	14,950 (16.8)
Any erectile dysfunction	41,676 (46.7)
Pre-existing erectile dysfunction	34,283 (38.4)
Any penile prosthesis surgery	2,107 (2.4)
Lives in a Metropolitan Statistical Area	73,213 (82.1)
Health Plan	
Comprehensive	1,915 (2.3)
HDHP/CDHP	10,386 (12.4)
HMO	9,096 (10.8)
POS/POS w/cap	7,028 (8.4)
PPO/EPO	55,451 (66.1)
Missing	5,329 (0.1)
Region	
Northeast	16,182 (18.1)
North Central	17,622 (19.8)
South	38,853 (43.6)
West	14,925 (16.7)
Unknown	1,623 (1.8)

\*Mean ± Std.

.0001) decreased between 2009 and 2019. In total, 2,107 men underwent IPP, however, only 14 lacked a concomitant ED diagnosis and were included in this analysis.

Figure 2 displays year-to-year cost trends — total and patient contribution — for per cycle CCH treatment, plication, and plaque grafting between 2009 and 2019. The median cost per patient for all 3 treatments increased over the study time-period: \$1,856 to \$3,196 for plication, \$2,233 to \$3,631 for plaque grafting, and \$6,940 to \$8,895 per cycle for CCH. From 2014 to 2019, median cost per patient increased 39%, 24%, and 28%

**Table 2.** Distribution of PD therapies for the analytic cohort

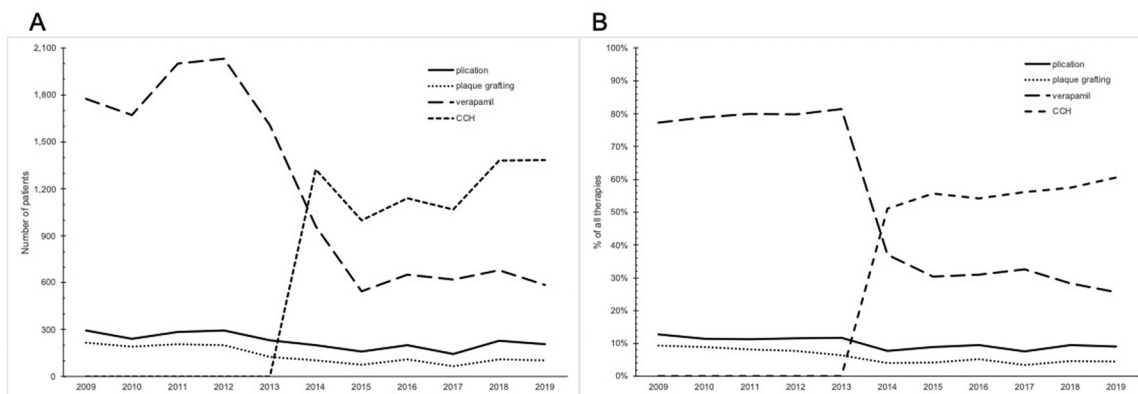
Type of therapy	Count (N = 21,605)
Only medical	18,135 (83.9%)
Only surgical	1,519 (7.0%)
Medical and surgical	1,951 (9.0%)
Type of intralesional injection	Count (N = 20,086)
Verapamil only	12,706 (63.3%)
CCH only	6,885 (34.3%)
Verapamil and CCH	409 (2.0%)
Any interferon alpha 2B	86 (0.4%)
Type of surgical therapy	Count (N = 3,470)
Plication only	1,943 (56.0%)
Plaque grafting only	959 (27.6%)
Plication and plaque grafting	537 (15.5%)
Any IPP	14 (0.4%)

for these therapies, respectively. Medication costs accounted for >95% of costs per cycle for CCH; a median of 2 cycles were required among patients who received CCH in this study. This translated to an increase in median total cost per patient for CCH from \$15,632 to \$17,755, which correlates to a 14% increase in costs. Median per patient costs for verapamil were significantly lower, starting at \$150 in 2009 and decreasing to \$60 in 2019. Out-of-pocket median patient contribution for surgical (ie, plication or plaque grafting) and per cycle intralesional CCH injection were similar over the study period and never exceeded \$300. Total costs and patient contribution for interferon alpha-2b and IPP were variable across the study period and are listed in Appendix 2, as well as yearly costs and patient contributions for all PD therapies.

## DISCUSSION

In this study, our goal was to identify trends in surgical treatment and intralesional injection therapy for PD before and after the FDA approval of CCH in December 2013, and the associated changes in cost of treatment. We found a steady increase in the use of CCH therapy for the treatment of PD, accompanied by a concomitant decrease in the use of surgical therapies during the study period. We also found that the cost of CCH is significantly higher than the cost of surgery for the management of PD.

Our findings regarding the use of CCH are consistent with previous analyses which show increasing utilization of intralesional injection therapy for PD accompanied by a decline in surgical correction of PD.<sup>5,8</sup> A population-based analysis by Sukumar et al. evaluating factors influencing choice of injection vs. surgical therapy showed that younger age, higher socio-economic status, and presentation to a surgeon with a high-volume



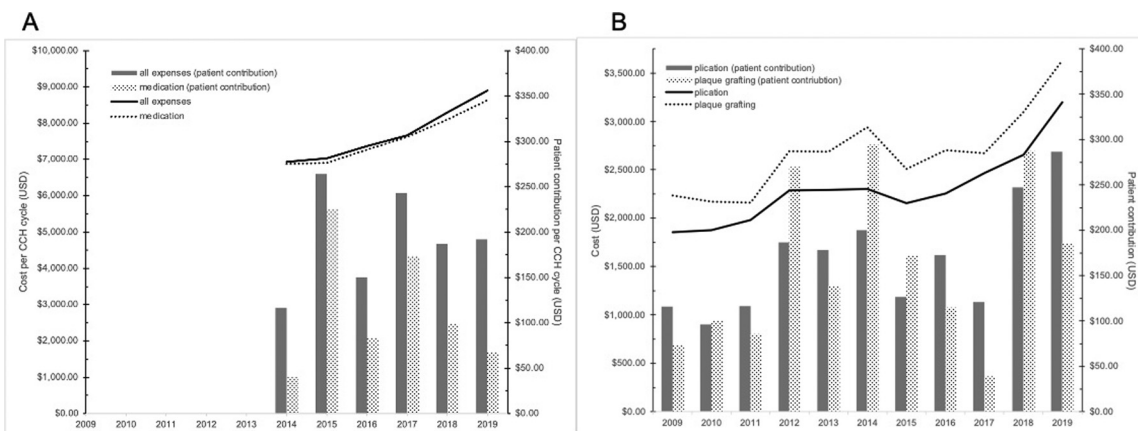
**Figure 1.** Trends in utilization of intralesional injection and surgical therapies for PD from 2009 to 2019. (A) Count. (B) Percent of all therapies.

clinical practice, were all associated with higher likelihood of receiving intralesional therapy.<sup>9</sup> Furthermore, patients presenting after CCH approval were 17% more likely to receive intralesional therapy. Our study demonstrated similar trends. Over 90% of patients treated for PD received intralesional in our series, consistent with current treatment patterns for PD among practicing urologists.<sup>5</sup> This may be the result of increasingly available evidence that CCH is a reasonable, efficacious, non-invasive first line therapy for PD.

We found that since 2014, CCH remains the most expensive PD treatment. Our series showed a cost of approximately \$6-9,000 per cycle for CCH injections with a median of 2 cycles correlating to a total cost of approximately \$15–20,000 per patient. Comparatively, the annual cost for any surgical therapy (including combinations of plication, plaque grafting, and IPP) ranged from approximately \$2–5,000. These results are complementary to the findings reported by Wymer et al. in their comparison of CCH injections, surgery, and penile traction therapy for PD.<sup>10</sup> Furthermore, our study found that the cost of these treatment options increased between 2014 and 2019. Median costs per patient increased between 15 and 40% with larger

absolute increases for CCH therapy, which was more expensive at baseline. In contrast, out-of-pocket patient contributions did not change significantly. The median patient contribution was \$100–300 per cycle for CCH injections correlating to a total cost of approximately \$300–800 per patient. Contemporaneous patient contribution for any surgical therapy ranged from \$150–500. Finally, 9% of patients required both medical and surgical therapy. This additive effect could result in total treatment costs approaching \$25,000 with out-of-pocket patient contribution essentially doubling.

Although many patients express a desire to discuss out-of-pocket costs with their physicians prior to initiation of treatment, only a small fraction of physicians and patients engage in a discussion about cost.<sup>11–13</sup> Loftus et al. used commercial claims data to investigate the cost of PD treatment with oral, injectable, and surgical therapies; they reported an increase in the annual cost of treatment for PD driven largely by increased use of CCH.<sup>8</sup> Notably, their report focuses on the overall cost of PD treatments. Our study that includes commercial claims data through 2019 and incorporates all procedure costs – including visit and anesthesia fees – is the most contemporary, comprehensive, and



**Figure 2.** Trends in total cost and patient contribution for PD therapies from 2009 to 2019. (A) CCH per cycle. (B) Plication and plaque grafting.

accurate reflection of overall and out-of-pocket costs to patients. In contrast to Loftus et al., we included the cost of treatment per cycle of CCH. This provides greater flexibility when counseling patients given that most patients required at least 2 cycles of this therapy. We also broke costs down by therapy and included the proportion of patients requiring multiple therapies, which permits providers to counsel patients on the additive cost of PD treatment. One other important distinction between our paper and the paper by Loftus et al. is the exclusion of IPP as a surgical option except in the absence of an ED diagnosis. This decision was made a priori to prevent inflation of PD-specific surgical costs when an IPP may have been indicated solely for severe ED. We anticipate these data to allow for a more complete discussion between patients and providers regarding their care.

Our analysis has a few limitations, primarily due to the use of a commercial claims database. This restricted our analysis to private sector US based health plans; our results cannot be generalized outside this patient population. Without individual patient data, we also could not quantify the severity of PD or patient satisfaction with treatment outcomes in this cohort. The commercial claims database also limited assessment of postprocedural costs: treatment of complications, nonroutine hospital/clinic visits, etc. Finally, our inclusion of IPP only in the absence of an ED diagnosis likely excluded patients with severe PD for whom IPP surgery is the appropriate primary treatment choice. This may have underestimated annual use and total costs of surgical therapy; however, the effect was minimized by assessing use and costs per procedure.

## CONCLUSIONS

Our study is the most contemporary, comprehensive, and accurate reflection of overall and out-of-pocket costs to patients. It found that CCH use has increased significantly since its FDA approval in 2013 and mirrors decreased use of intralesional verapamil and surgical treatment for PD. CCH is significantly more expensive than any surgical treatment option, however, the out-of-pocket patient contribution for surgery and CCH are similar. This information allows for a complete discussion of PD treatment between patients and providers.

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## STATEMENT OF AUTHORSHIP

Conceptualization, E.M. and A.M.; Methodology, E.M., D.P., and A.M.; Formal Analysis, D.P.; Investigation D.P.; Writing - Original Draft, E.M.; Writing - Review & Editing, E.W., T.Q., D.P., and A.M.; Visualization, E.W., T.Q., and E.M.; Supervision, A.M.

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## APPENDIX 1. CPT AND HCPCS CODES FOR DIAGNOSIS AND TREATMENT OF PEYRONIE'S DISEASE

Procedure	Code
Verapamil (medication)	J3490
Verapamil (all expenses)	J3490, 54200, 54235, 64450, 96372, 99212, 99213, 99214
CCH (medication)	J0775, J0775-JW
CCH (all expenses)	J0775, 54200, 54235, 96372, 20527, 99212, 99213, 99214, 99215, J0270, J2370, J2760
Interferon alpha 2B (medication)	J9214
Interferon alpha 2B (all expenses)	J9214, 54200, 96401, 96413, 96361, 96375, 99212, 99213, 99214
Surgical plication	54360 00920
Surgical excision of plaque and grafting	54100 54110 54111 54112 00920 17311 C1762 C1763
Insertion of penile prosthesis	54400, 54401, 54405, 54406, 54408, 54410, 54411, 54415, 54416, 54417, C1813, C2622, 00920, 00938

## APPENDIX 2. YEARLY TOTAL COST AND PATIENT CONTRIBUTION FOR PD THERAPIES FROM 2009 TO 2019

Median cost per patient (USD)												
Year	Intralesional injection therapy								Surgical therapy			
	Verapamil		CCH (per cycle)		CCH (total)		Interferon alpha 2B		Any	Plication	Plaque grafting	IPP
	Medication	All expenses	Medication	All expenses	Medication	All expenses	Medication	All expenses				
2009	\$36.30	\$150.20	–	–	–	–	\$606.10	\$1,024.00	\$2,278.40	\$1,856.10	\$2,233.00	\$1,865.80
2010	\$33.90	\$134.40	–	–	–	–	\$610.00	\$1,353.00	\$2,242.00	\$1,875.70	\$2,170.50	\$2,592.20
2011	\$38.40	\$132.10	–	–	–	–	\$99.00	\$439.00	\$2,521.90	\$1,981.70	\$2,158.20	\$2,512.60
2012	\$30.00	\$115.40	–	–	–	–	\$844.00	\$1,060.60	\$2,858.20	\$2,285.10	\$2,694.70	\$3,937.70
2013	\$29.00	\$96.50	–	–	–	–	\$869.40	\$1,022.00	\$2,723.40	\$2,292.50	\$2,687.80	
2014	\$22.00	\$70.00	\$6,875.50	\$6,939.60	\$15,433.40	\$15,631.90	\$22.00	\$301.00	\$3,294.90	\$2,304.90	\$2,938.00	\$4,702.80
2015	\$20.50	\$86.70	\$6,901.00	\$7,033.90	\$20,174.00	\$20,267.30	\$522.30	\$765.90	\$2,825.50	\$2,153.00	\$2,507.50	\$3,511.50
2016	\$22.60	\$85.50	\$7,272.00	\$7,369.00	\$15,991.20	\$16,527.80	\$1,777.10	\$1,777.10	\$3,131.50	\$2,252.50	\$2,701.00	
2017	\$18.20	\$70.00	\$7,626.10	\$7,667.50	\$17,100.00	\$17,536.90	\$946.70	\$1,025.10	\$3,099.70	\$2,465.00	\$2,670.60	\$10,939.10
2018	\$27.00	\$69.40	\$8,102.00	\$8,301.10	\$18,940.20	\$20,429.10	\$1,200.00	\$1,837.00	\$3,700.90	\$2,655.50	\$3,096.80	\$1,525.90
2019	\$19.20	\$60.20	\$8,634.60	\$8,895.10	\$17,004.10	\$17,755.20	\$912.00	\$3,029.50	\$4,754.60	\$3,196.00	\$3,630.90	

Median patient contribution (USD)												
Year	Intralesional injection therapy								Surgical therapy			
	Verapamil		CCH (per cycle)		CCH (total)		Interferon alpha 2B		Any	Plication	Plaque grafting	IPP
	Medication	All expenses	Medication	All expenses	Medication	All expenses	Medication	All expenses				
2009	\$0.00	\$10.20	–	–	–	–	\$0.00	\$90.00	\$128.50	\$116.00	\$73.60	\$0.00
2010	\$0.00	\$6.20	–	–	–	–	\$0.00	\$0.00	\$100.00	\$96.00	\$100.00	\$514.00
2011	\$0.00	\$4.90	–	–	–	–	\$0.00	\$38.00	\$146.60	\$116.40	\$85.70	\$1,150.70
2012	\$0.00	\$5.50	–	–	–	–	\$0.00	\$35.00	\$237.70	\$186.70	\$269.50	\$672.00
2013	\$0.00	\$1.50	–	–	–	–	\$16.00	\$92.60	\$163.60	\$178.10	\$138.70	
2014	\$0.00	\$0.00	\$40.00	\$116.50	\$90.60	\$300.00	\$0.00	\$0.00	\$243.60	\$200.30	\$294.30	\$0.00
2015	\$0.00	\$1.30	\$224.40	\$263.80	\$412.20	\$600.00	\$0.00	\$225.00	\$188.50	\$126.30	\$172.10	\$587.30
2016	\$0.00	\$3.40	\$83.30	\$150.00	\$180.00	\$480.00	\$572.00	\$572.00	\$182.80	\$172.40	\$115.00	
2017	\$0.00	\$0.40	\$173.00	\$242.90	\$561.50	\$755.80	\$299.50	\$337.00	\$153.50	\$121.10	\$39.00	\$2,333.40
2018	\$0.00	\$0.00	\$98.80	\$186.90	\$200.00	\$465.00	\$240.00	\$420.00	\$299.40	\$247.20	\$287.00	\$305.20
2019	\$0.00	\$0.00	\$68.10	\$192.10	\$127.90	\$372.80	\$250.60	\$430.60	\$490.30	\$286.40	\$186.10	