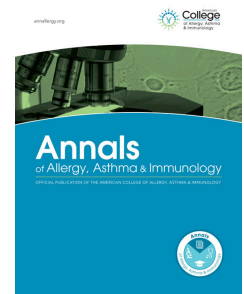


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Recombinant zoster vaccine administration in an allergy/immunology practice: a medical and economic case

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Abbreviations: CMS: Centers for Medicare and Medicaid Services; CPT: Current Procedural Terminology; GSK: GlaxoSmithKline; MA: Medical assistant; PI: Process improvement; RZV: Recombinant Zoster Vaccine; VZV: Varicella Zoster Virus

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Thousands of US adults are killed by vaccine-preventable diseases each year,¹ however, adult immunization rates in the US remain low, ranging from 8-64%.² Increasing vaccination rates, and therefore preventing disease, requires an establishment of value by healthcare professionals and improved access to vaccinations.¹ Allergists/immunologists should consider implementing routine vaccine administration for adolescents and adults into their practices. More than half of outpatient visits in the US are to specialists.³ Many allergists rely on primary care providers to meet the adult population's vaccination needs, but only 32% of internists and 29% of family medicine providers assess vaccinations at every visit.⁴ Thus, many patients are unaware and uneducated about vaccine recommendations.¹ It is the job of all medical providers, including specialists, to provide the information and supply of vaccinations to patients. Allergy clinics are well-equipped for vaccine delivery. Moreover, immunosuppressive therapies that attenuate vaccination response and pre-dispose patients to reactivation of infections are being increasingly used in medical practices, and pre-vaccinating patients before initiating some immunosuppressive agents is recommended.⁵

Herpes zoster (HZ) affects 500,000 US adults over 60 years each year⁶ and the incidence has increased greater than four times over the last six decades.⁷ Licensed by the FDA in October 2017 and marketed as SHINGRIX®, recombinant zoster vaccine (RZV) is a subunit vaccine containing recombinant varicella zoster virus (VZV) glycoprotein E combined with a novel adjuvant (AS01B).⁸ RZV does not contain live VZV like the previous shingles vaccine. RZV is recommended by the Advisory Committee on Immunizations Practice (ACIP) for patients 50 years and older for HZ prevention⁸ and is administered as a 2-dose series via the intramuscular

route, with the second dose given 2-6 months after the first dose. Revaccination with RZV is recommended by the ACIP for those patients previously vaccinated with the live shingles vaccine. RZV efficacy can be as high as 97.9% for HZ prevention and 100% for postherpetic neuralgia prevention,⁹ but RZV immunization rate is only 30%.¹⁰ While there is a need for increased vaccination administration, many medical clinics are not offering vaccine administration due to the logistics of ordering and administering vaccines and beliefs that it is not cost-effective.¹¹

As part of a process improvement (PI) project, RZV use in a solo allergy practice was evaluated over 12 months (June 28, 2018 – June 27, 2019). The age and gender of patients, dates of injections and reimbursement amounts were associated with each RZV injection. Microsoft Excel was used to organize data and calculate profit margins and vaccine adherence rates. . Patients receiving RZV 65 years and older had private insurance. There were no Medicaid or Medicare patients in this PI program as this practice was not contracted with Medicaid and did not have the ability to submit a pharmacy benefit claim for RZV under Medicare (RZV is a part D benefit) during the study period.

Seventy-one doses of RZV were administered to 58 patients (63.8% female). The average patient age was 57.8 years. Thirteen patients (22.4%) received the second dose in this clinic, completing the two-shot series. Of the 45 patients who did not receive the second RZV injection, 13 patients (22.4%) were >6 months (“overdue”) since the first injection, and 11 patients (19.0%) were <2 months since the first injection. Thus, there were 34 patients eligible to receive

their second injection who had no documentation of receipt of the second RZV vaccination.

Due to national RZV supply shortages, patients were occasionally referred to the local economy for completion of the series.

The practice cost for RZV from GSK was \$134.46 until May 1, 2019 and \$138.49 after May 1, 2019. RZV was bought from GSK because there is a 2% discount for paying early for the vaccine. However, in order to augment practice supply during national shortages, RZV was also bought from the distributor McKesson for \$146.13. The first McKesson RZV vaccine was used in this practice on June 10, 2019.

The 2019 Centers for Medicare and Medicaid Services Physician Fee Schedule¹² for the practice locality in Tennessee does not price for RZV (CPT 90750) but reimburses \$15.73 for one vaccine administration (CPT 90471) and \$12.09 for two or more vaccine administrations (CPT 90472).

The average insurance payer reimbursement for RZV was \$154.74 and for vaccine administration was \$18.09. Comparison of de-identified insurance payer reimbursement rates for RZV and vaccine administration can be found in Table I. Using the GSK price of RZV of \$134.46, the average profit margin without the vaccine administration fee was \$20.28. As allergist/immunologists do not sell vaccine alone, the total profit margin, including vaccine administration reimbursement, was \$38.11. The average profit margin when RZV is bought from the distributor McKesson was \$26.44.

If RZV administration is both a sound medical and economic model, why are more allergists/immunologists not implementing RZV administration into their practices? While vaccination outsourcing to community-based pharmacies has provided convenience of walk-in administration at more flexible hours,¹¹ it has also established an adherence barrier. If a physician recommends vaccinations to patients in-office but does not have the means to administer them and therefore refers the patients to a community-based pharmacy or outsourced vaccination clinic, the physician has missed the opportunity to prevent disease. Patients lead busy lives and making arrangements to go to multiple places to receive vaccinations is inconvenient and not ideal. The difficulties of getting vaccinations to patients, especially adults who are not as routinely monitored, is an enormous barrier to adherence.. Another major barrier to vaccine administration is lack of availability within the healthcare provider's office.¹⁰ The leading reason why patients receive a vaccination is because their physician both recommends and administers it.¹ As practitioners of evidence-based medicine, allergists/immunologists should consider implementing all eight adolescent and adult vaccine lines into their practices (i.e. Tdap, influenza, both pneumococcal vaccines, human papilloma virus-9, meningitis ACWY, meningitis B and RZV).

Many clinics are not providing vaccinations due to the concern that vaccination administration has a low or negative profit margin.¹¹ While practicing medicine to help patients lead healthier lives is what should drive practitioners' actions, concerns about the economic feasibility of implementing a vaccine line are valid. However, the average RZV profit margin was \$38.11 in this study. Insurance payers may reimburse less for the product but reimburse more for the

vaccine administration. For example, Payer 2 reimbursed \$140.00 for RZV and \$25.74 for administration (total \$165.74), while Payer 3 paid \$144.20 for RZV and \$20.88 for administration (total \$165.08) (Table I). All insurance payers in this study reimbursed for a positive profit margin, and 75% reimbursed for a total profit margin of greater than \$30. The average pay for a medical assistant (MA) in the Memphis, TN, area is \$12-\$15/hour therefore one RZV administration pays for greater than two hours of MA wages. It is important to note that these results are specific to the state of Tennessee.

RZV administration, as a part of national routine ACIP recommendations for adults 50 years and older, should be implemented into allergy/immunology practices because of its clinical utility and effectiveness in combating sequelae from infection with HZ. While the priority of every practitioner should be to provide exceptional medical care to every patient, with the implementation of any additional clinical utility, such as vaccine administration, into a practice comes questions about the economic feasibility of its execution. It was found in this PI project that RZV administration at a solo allergy practice is clinically relevant and also economically feasible as evidenced by the 73 doses administered during a 12-month PI project with an average profit-margin of \$38.11. RZV can be purchased from GSK in units of 10 doses and expiration dates exceed two years from the date of receipt. Allergists/immunologists are best equipped to implement robust immunization product lines given their infrastructure of administering injections and their training in immunology. Therefore, allergists/immunologists should implement RZV vaccination into their routine health maintenance practice because it serves as both a sound medical and economic model.

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Table I: Insurance payer reimbursement rates and profit margins

Insurance Payer	n	Shingles Buy & Bill CPT 90750	Vaccination Administration CPT 90471	Total Reimbursement	GSK Price for RZV	Profit Margin WITHOUT Vaccination Administration	TOTAL PROFIT MARGIN
1 (2018 & 2019)	25	\$ 159.60	\$ 23.68	\$ 183.28	\$ (134.46)	\$ 25.14	\$ 48.82
2 (2018 & 2019)	1	\$ 159.60	\$ 19.66	\$ 179.26	\$ (134.46)	\$ 25.14	\$ 44.80
3 (2019)	3	\$ 161.50	\$ 12.00	\$ 173.50	\$ (134.46)	\$ 27.04	\$ 39.04
3 (2018)	18	\$ 156.80	\$ 12.00	\$ 168.80	\$ (134.46)	\$ 22.34	\$ 34.34
4 (2018 & 2019)	7	\$ 140.00	\$ 25.74	\$ 165.74	\$ (134.46)	\$ 5.54	\$ 31.28
5 (2018)	3	\$ 144.20	\$ 20.88	\$ 165.08	\$ (134.46)	\$ 9.74	\$ 30.62
5 (2019)	2	\$ 144.20	\$ 16.93	\$ 161.13	\$ (134.46)	\$ 9.74	\$ 26.67
6 (2018)	4	\$ 142.80	\$ 10.00	\$ 152.80	\$ (134.46)	\$ 8.34	\$ 18.34
6 (2019)	1	\$ 142.80	\$ 9.11	\$ 151.91	\$ (134.46)	\$ 8.34	\$ 17.45
7 (2018)	2	\$ 126.00	\$ 13.50	\$ 139.50	\$ (134.46)	\$ (8.46)	\$ 5.04
7 (2019)	2	\$ 186.00	\$ 11.01	\$ 197.01	\$ (134.46)	\$ 51.54	\$ 62.55
8 (2018 & 2019)	1	\$ 179.00	\$ 10.00	\$ 189.00	\$ (134.46)	\$ 54.54	\$ 54.54
9 (2018 & 2019)	1	\$ 147.08	\$ 10.00	\$ 157.08	\$ (134.46)	\$ 12.62	\$ 22.62
Average		\$ 154.59	\$ 17.98	\$ 172.57	\$ (134.46)	\$ 20.28	\$ 38.11

(CPT: Current Procedural Terminology; GSK: GlaxoSmithKline; RZV: Recombinant Zoster Vaccine); Note that for insurance payers with '(2018 & 2019)' next to their respective number signifies that that particular insurance company had the same reimbursement rates for CPT 90750 and CPT 90471 in both 2018 and 2019.