



Perspective

Venom shortages

What's an allergist to do? Part 1, the issues

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Venom immunotherapy (VIT) for the management of stinging insect allergy has been an important service provided by allergists for nearly 4 decades.¹ Venom extracts are unique in a number of ways. Directly measured in micrograms compared with potency measures as used in other forms of immunotherapy, they were also the first standardized extracts used in clinical practice. In addition, they are the only approved treatment for the prevention of anaphylaxis. In 1978, the landmark work published by Hunt et al² demonstrated that whole-body extracts were no more effective than placebo, but that purified venom extracts were highly effective.² With expanded availability of venom products and improved efficacy compared with previous therapy, their use became the standard of practice.

For almost 40 years, allergists in the United States could choose between 2 manufacturers of venom products.³ Over the years, the occasional temporary shortages of specific venoms or variation in specific species availability within a genus were at worst an inconvenience.³ As a result, many allergists used these similar products interchangeably. In addition to the technical components of the management of venom allergy, concurrent issues were related to cost and reimbursement of venom services.

The pricing of medical services in the United States is a complicated process. It involves a system in which relative value

units (RVUs), are determined by the American Medical Association's Relative Value Scale (RVS) Update Committee (RUC), including for venom immunotherapy.⁴ The RUC is a unique multispecialty committee dedicated to describing the resources required to provide physician services that the Centers for Medicare & Medicaid Services (CMS) considers in developing RVUs. Each procedure code is assigned a certain number of RVUs, which are multiplied by a conversion factor dollar amount and a geographic price cost index (GPCI) to determine how much an individual physician is paid. The Center for Medicare and Medicaid Services (CMS) uses a complicated formula to calculate RVUs that involves the time and intensity of physician work as well as practice overhead.⁵ Practice overhead includes direct costs (clinical staff time; clinical equipment; and supplies) and an allocation for indirect overhead. If the direct cost amounts CMS uses in its formula increase, then reimbursement goes up; if those costs go down, reimbursement decreases. CMS delegates this work to the RUC, but it retains authority to accept or reject the RUC's work.

The RUC consists of 31 members, 21 of whom are appointed by national medical specialty societies.⁴ In 2017, for the first time in years, an allergist/immunologist was elected to the RUC. In addition, all the national specialty societies have advisors to the RUC. These advisors do not sit on the committee, but they represent their specialty when issues come before the RUC.⁴

Many factors result in the variation of pricing of medical services in different regions of the country. These include the penetration of managed care, local competition among insurance companies, as well as the relative proportion of patients with Medicare, Medicaid, and private insurance coverage. A significant factor in the variability of fee schedules, including venom immunotherapy, is CMS's Geographic pricing cost index (GPCI).⁵ The GPCI takes into account regional differences in the costs of delivering medical services.

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Doctors in rural areas tend to have lower acquisition of goods and services compared with doctors in urban areas. When implemented in 1989, the economic adjustments on the surface seemed valid. However, as time has progressed, supplies and services are more commonly purchased from national vendors, creating less disparities in cost by region. In recent years debate over the GPCI has become more political, pitting the higher-paid large states against the states with more rural populations. Although the GPCI only has a direct effect on Medicare pricing, Medicare fee schedules are often the basis of fee schedules used by private insurance companies. When discussing prices on a service that is universally profitable, like the codes for visits, the debate is about profit margins. However, for a service priced close to the acquisition cost, such as venom immunotherapy, the discussion turns into one of very thin profit margins or even loss.

For decades, delivering VIT resulted in minimal returns for allergists in many regions of the United States but could be offset by the earnings in evaluation and management codes and venom testing. Many of those physicians who continued to offer VIT were driven by the goal of being a “full service allergist” and doing what was best for the patient. In the 2016 Advocacy Council of the American College of Allergy, Asthma and Immunology survey of membership, receipts for actual prices paid to manufacturers (as opposed to list prices), were reviewed and substantial differences from the previous venom cost evaluations were found. After the Advocacy Council petitioned the RUC, there was an increase of 16% to 39% in RVUs for VIT that translated into an increase in venom reimbursement for 2017. The hope was that the debate of allergists regarding delivering venom allergy shots would turn away from economic considerations.

However, in October 2016, ALK announced an interruption of venom supplies to the US market. This drop in production seemed, at the time, to be another of the temporary inconveniences that have affected venom extract supplies. This was a little more significant than past supply problems because of the projected length of the disruption, and concerns about Jubilant HollisterStier (JHS)’s ability to immediately meet the North American demand for venom products. The national allergy organizations convened an expert panel, who made recommendations on how best to manage what, at the time, was considered a short-term problem. Suggestions included recommendations to be selective about who would best benefit from VIT, decrease the maintenance dose of VIT, and to increase the interval of injections.³

Only one supplier of venom is now in the United States. Part 2 of this article will discuss more issues related to cost and supply, as well as addressing potential solutions, including actions individuals and societies might consider.

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