



Perspective

Venom shortages

What's an allergist to do? part two: potential solutions

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The surprise announcement in March 2018 that ALK was leaving the North American venom market permanently changed the landscape for venom immunotherapy. The American College of Allergy, Asthma and Immunology (College) and the American Academy of Allergy, Asthma and Immunology (Academy) have jointly communicated with Jubilant HollisterStier (JHS) about long-term product and supply issues. Even with reassurances of price and supply stability given to the 2 national allergy organizations by the remaining venom vendor, the Advocacy Council of the American College of Allergy, Asthma and Immunology continued to receive calls and emails expressing concerns about pricing and availability of venom extracts. Based on objective data received from concerned members, as of the spring and summer of 2018, the prices being invoiced were not substantially different from those the Advocacy Council collected in 2016. However, in 2018, the new catalogue pricing showed significant increases, and many allergists, especially those in solo or small groups, who previously had not bought venoms from JHS were being invoiced at the new catalogue prices.

The pricing of allergy extracts is based on list prices and discounts of those list prices, which are influenced by a number of factors, including volume of purchases of all products. The Relative Value Scale (RVS) Update Committee (RUC) knows that doctors

receive discounts on base prices and RVUs are based on average actual prices paid, not published list prices. Now that there is a single supplier, one would expect that discounts would evaporate and list prices would rise.

Under the recent pricing structures, neither allergists nor the manufacturers are satisfied with the economic viability of venom immunotherapy (VIT). Many physicians continued to provide services to meet the needs of patients. Anecdotal reports from members and sales numbers from industry indicate the number of people seeking treatment for venom allergy may be decreasing for reasons that are not yet clear. Although possibly the incidence of venom allergy is declining, other nonmedical explanations are also possible. Anecdotal reports have been made of allergists electing to no longer offer VIT, resulting in decreased access to this critical life-saving therapy. Concomitant changes in the delivery of health care, including high-deductible plans, may cause patients to defer seeking treatment because of high out-of-pocket costs. Awareness of the lifesaving benefits of VIT has always been low among non-allergist health care providers, and could be waning further.¹ Public awareness of the benefits of VIT could also be decreasing.² This entire, troubling trend carries with it the unintended consequence of losing this life-saving treatment option for venom-allergic patients.

What can our allergy societies do in response to these challenges? We have collected and will continue to collect receipts of prices paid from members and, if significant increases are found, we can appeal to the RUC for an increase in RVUs. It is also possible to go directly to Centers for Medicare & Medicaid Services (CMS) and ask for increased reimbursement. This was done in September 2018, and the new fee schedules effective January 2019 reflect increases in reimbursement for VIT. However, this may lead to an endless cycle of price increase and fee changes in which allergy

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doctors never truly achieve the goal of a fair price for the services provided and are always behind in reimbursement vs the cost of delivering the service. The College and the Academy continue communications with JHS about how we can help insure an adequate supply for our patients but cannot negotiate prices or discounts.

Another possible avenue is a public education campaign done in partnership with lay organizations, such as Allergy and Asthma Network and Allergy and Asthma Foundation of America. Such a campaign will be expensive and long, and meaningful metrics to judge success will be difficult to obtain. Enlisting the help of patients with personal experience could help put a human face on this public health issue.³

What can individual practices do in response to these challenges? Some larger providers in anticipation of the price increases stockpiled adequate supplies for their patients. When the current shortage subsides, additional practices may want to consider this strategy, because lyophilized VIT extracts have long shelf lives, and additional supply disruptions seem inevitable. Individual practices should be active in public debate of this issue, publishing in local media, and participating in national advocacy activities, including the Advocacy Council Strike Force and the Allergy and Asthma Network Capitol Hill Allergy Awareness Day. Individual practices can be reassured that even though the return on VIT is marginal, they can hope for an increased referral base if they continue to be a “full service” for all allergy services.

The Food and Drug Administration (FDA) has been clear that the pricing of drugs is beyond their responsibility. However, lifesaving drugs subject to shortage is within their purview. Reports have been made of practices electing to cease providing VIT because of the cost and difficulties in obtaining venom extracts, referring their

patients to other allergists. Only time will tell whether the doctors making these difficult decisions will be judged wise or short sighted. How should we as the specialists most capable of providing this life-saving treatment option proceed? Should we seek orphan drug status for VIT? Should we ask the FDA to fast track approval of European venom extracts? Some even suggest the FDA should loosen manufacturing standards, but many would argue this proposal is too risky. Advocates could petition Congress to provide funding to subsidize a process to bring additional VIT products to market in the United States.

Clearly, having a single supplier of venom extracts is suboptimal for many reasons, including supply and competitive pricing, because the existence of competition tends to keep price increases more manageable. Recent experience suggests that intermittent supply interruptions of allergy extracts can happen. In the production of any biological product, such as immunotherapy extracts, supply issues are inevitable. Having a single North American supplier puts VIT patients at unacceptable risk. Individual allergists, national allergy societies, and allergy patient advocacy groups must all remain engaged to find a solution for this “at risk” group of patients.

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