



VIA ELECTRONIC DELIVERY

May 13, 2024

Ryan Howe, PhD

Director, Hospital & Ambulatory Policy Group
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
7500 Security Boulevard
Baltimore MD 21244-1850

Dear Dr. Howe,

On behalf of Jubilant HollisterStier Allergy ("HollisterStier"), we are writing to express our concerns related to the Centers for Medicare & Medicaid Services' ("CMS" or "the Agency") current reimbursement for CPT codes 95145-95149 *Supervision of preparation and provision of antigens for allergen immunotherapy*; 1-5 single stinging insect venoms, respectively, as listed in Attachment "A". Specifically, we are concerned that the current reimbursement for these codes under Medicare's physician fee schedule no longer appropriately and accurately reimburses for the practice expenses as required by those procedures.

The current physician reimbursement for these codes is based on the Harvard valuation and has never been surveyed by the RUC, which stated in February 2001 that the CPT modifications to the definitions for these codes were editorial and did not involve a change in the service. The practice expense inputs have not been reviewed for over twenty years, despite numerous federal and state regulatory updates and guideline changes that have led to practice changes. Further, the professional liability and practice expense inputs for these codes were not reviewed in January 2016 when code 95165 was reviewed by the RUC and by CMS. Additionally, the cost to manufacture venom immunotherapy has drastically changed since 2001 due to increased labor and raw material costs.

Based on the proposed changes that we provide in Attachment "B", we request that CMS updates the practice expenses of codes 95145-95149, effective with the 2025 Medicare Physician Fee Schedule. Alternatively, we request that these codes are referred to the AMA RVS Update Committee to address the physician work, practice expense, and professional liability insurance of these procedures.

I. Background

Jubilant HollisterStier has been a leading force in the allergic extract industry for over 100 years. Founded in 1921 in Spokane, Washington. HollisterStier is a wholly owned subsidiary of Jubilant Pharmova ("Jubilant"), an integrated global pharmaceutical company offering a wide range of products and services to customers across geographies. To learn more about Jubilant, visit <https://www.jubilantpharma.com/>.

Jubilant HollisterStier's portfolio includes a variety of allergy extracts that include but are not limited to dog hair, cat hair, mite, and venom extracts, among others. HollisterStier also offers relevant skin test devices and supplies required for venom therapy. Thus, HollisterStier has significant experience in allergy specialty pharmaceutical products.

Venom immunotherapy is the venom extract for testing and treating honeybees, white-faced hornets, yellow hornets, wasps, and yellow jackets, which are available in single, five, and 12-dose vials. Venom manufacturing is a labor-intensive process, requiring the collection of thousands of pounds of wasps and other vespids each year and the manual dissection of venom sac with tweezers, which takes 520 staff hours to extract 130,000 insects for one batch of raw material. Venom processing also requires significant investment in venom-related equipment and infrastructure.

Before January 1, 1995, venom products were reimbursed under respective J-codes. Due to the infrequent use and limited budget impact on the Medicare Trust Funds, CMS decided to retire the product-specific J-codes and fold the product reimbursement within the relevant CPT codes, 95145-95149.¹

II. CPT Codes Do NOT Reflect the Appropriate Practice Expense

The practice expense inputs for codes 95145-95149, when surveyed in 2001 only account for swab-pad, antigen, syringe, and gloves, while the most recently surveyed 95165 code accounts for surgical cap, gloves, gown, mask, syringe, alcohol, swab-pad, paper towel, antigen vial transport envelope, color-coded cap and vial, label, scrub brush in addition to antigen. The descriptors for CPT codes 95145-95149 and 95165 can be found in Attachment A. Attachment “B” lists the practice expense inputs of each of the codes. The practice expense inputs for codes 95145-95149 fall short in what is required for each procedure.

The 2019 standards for allergen extract compounding under USP Chapter 797² are applicable to the practice expense and physician work of codes 95145-95149 and are listed in Attachment “C,” allergy mixing practices. Based on the updated standards, each procedure requires sterile powder-free gloves, face mask, hair net/beard net, gown/sterile garb, isopropyl alcohol, paper towel, sterile empty vials, albumin saline, in addition to allergenic extract. The same standards also require significantly more annual training for the provider under USP 797, including competency observation, media fill test, gloved fingertip test, and corrective actions. Additionally, the venom cost has increased to \$ 481.50 for a 5-dose wasp as of April 1, 2024.

III. Conclusions

It is critical that in setting payment for physician services, CMS considers regulatory and practice changes involved in the preparation and administration of venom injection that have changed since 2001. The failure to consider these factors has led to reduced access to care for patients. As the reimbursement for venom immunotherapy is financially unstable, an increasing number of physician offices are no longer able to offer this service, as supported by *Venom Immunotherapy Reimbursement: A Time for Change* listed in Attachment “D.”

HollisterStier urges CMS to consider the unique characteristics and challenges associated with venom immunotherapy, which is labor-intensive to manufacture. Re-surveying the practice expense is crucial to patient access to venom immunotherapy. Therefore, Jubilant HollisterStier is writing to request that CMS refer the venom immunotherapy codes 95145-95149 to the AMA’s RUC for their input.


¹ Federal Register Vol. 59, No. 121, June 24, 1994.

² [USP Section 21 – Compounding Allergic Extracts](#).



Thank you in advance for considering our concerns. Should you have any questions concerning our recommendations, please contact me at Kyle.Ferguson@jubl.com or at (267) 724-9263.

Sincerely,

Signature: 

Name: R. Kyle Ferguson

Title: CEO

Organization: Jubilant HollisterStier

Attachment A

CPT Codes	Description
95145	Supervision of preparation and provision of antigens for allergen immunotherapy; single stinging insect venom
95146	Supervision of preparation and provision of antigens for allergen immunotherapy; 2 single stinging insect venoms
95147	Supervision of preparation and provision of antigens for allergen immunotherapy; 3 single stinging insect venoms
95148	Supervision of preparation and provision of antigens for allergen immunotherapy; 4 single stinging insect venoms
95149	Supervision of preparation and provision of antigens for allergen immunotherapy; 5 single stinging insect venoms

Attachment B-D are in Separate Files