Herpes Zoster Vaccination: Benefits and Barriers

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The incidence and severity of herpes zoster increases with advancing age, as does its most common complication—postherpetic neuralgia (PHN). The most effective management strategy for herpes zoster and PHN is prevention of the disease through vaccination, particularly in the most vulnerable patient population (ie, individuals aged 70 years or older). The Shingles Prevention Study demonstrated that vaccination reduced the incidence and severity of herpes zoster, as well as the incidence of PHN. Despite the benefits of zoster immunization, administration of the vaccine may be met by certain barriers, including issues related to reimbursement, storage, and availability of the vaccine. Educating physicians and the public about the importance of herpes zoster prevention, while underscoring the pain associated with this disease and the challenges in managing it, will help to overcome these barriers.

Herpes zoster is a painful disease with complications that can be debilitating—especially in elderly individuals, who are at increased risk of reactivation of the varicella zoster virus (VZV). Treatment of patients who have herpes zoster and its complications, primarily postherpetic neuralgia (PHN), is difficult as a result of various factors. For example, some patients may have increased sensitivity to narcotic analgesics and anticonvulsants used to manage PHN. Also, renal function declines with age and older adults may have increased side effects to antiviral medications. Consequently, prevention of herpes zoster infection through vaccination is the preferred approach to this disease.

The Advisory Committee on Immunization Practices of the United States Centers for Disease Control and Prevention recommends use of the herpes zoster vaccine in adults aged 60 years or older, regardless of whether they have had herpes zoster in the past.1 In the Shingles Prevention Study,2 a randomized double-blind placebo-controlled trial of the herpes zoster vaccine, more than 19,000 adults aged 60 years or older received the vaccine, while more than 19,000 others received placebo. Results showed that vaccine efficacy for reducing the incidence of herpes zoster and PHN was 51.3% and 66.5%, respectively, in all subjects receiving active vaccine treatment compared with placebo (P<.001) (Table).2

The burden of illness caused by herpes zoster—the primary endpoint of the Shingles Prevention Study—was a measure of incidence, severity, and duration of zoster-related pain and discomfort.2 Compared with placebo, the zoster vaccine reduced the burden of zoster-associated illness by 61.1% among all subjects aged 60 years or older (P<.001) (Table).2 The most frequent adverse effects associated with the herpes zoster vaccine included erythema, pain, tenderness, and swelling at the injection site, as well as headache.2

Despite the importance of herpes zoster immunization and the demonstrated effectiveness of the zoster vaccine, vaccine uptake is suboptimal as a result of a variety of barriers to immunization. These barriers include storage requirements, vaccine cost and reimbursement, and vaccine availability (Figure).

Vaccine Administration

The herpes zoster vaccine approved by the US Food and Drug Administration is a live attenuated VZV vaccine indicated for the prevention of herpes zoster in
The herpes zoster vaccine must be administered immediately after reconstitution to minimize loss of potency. Reconstituted vaccine must be used within 30 minutes, and the vaccine should not be refrozen after reconstitution.

Vaccination in Elderly Patients
Because the incidences of herpes zoster and PHN increase with age, consideration should be given to vaccination of any individual aged 70 years or older. The elderly segment of the population may have the greatest complication rate to drug treatment for herpes zoster, and elderly individuals may be least able to tolerate adverse effects of drug treatment—including treatment with antiviral medications, topical anesthetics, systemic analgesics (eg, opioid analogs), and psychotropic drugs (eg, tricyclic antidepressants). The costs, benefits, and risks of medications administered long-term for the management of herpes zoster and PHN should be weighed against the costs, benefits, and risks of administration of the herpes zoster vaccine for each patient. Such a risk-vs-benefit analysis is especially useful for the oldest population segment (ie, age ≥85 years).

Vaccine Reimbursement
Another complication associated with herpes zoster immunization involves difficulties with reimbursement. The standard Medicare program does not provide reimbursement directly for the herpes zoster vaccine. For patients who have Medicare as their primary insurer, the use of the herpes zoster vaccine must be submitted under the Medicare Part D prescription drug coverage plan, and patients must meet requirements of the Medicare-approved provider of the plan with regard to deductibles and copays. Physicians will need to bill patients for the vaccine and the administration fee. Patients can then submit their claim to their Part D plan for reimbursement. Enrollees may be required to submit a paper claim to receive reimbursement for the vaccine and administration charges.

Some Medicare-approved providers of the Part D plan require prior authorization of vaccinations for approval of:

- **Vaccine Storage Requirements**
  - Vaccine must be stored at temperature of −15°C (5°F).
  - Vaccine must be reconstituted immediately upon removal from the freezer using only the supplied diluent.
  - Vaccine must be administered immediately after reconstitution to minimize loss of potency.
  - Reconstituted vaccine must be used within 30 minutes.

- **Vaccine Reimbursement**
  - Standard Medicare reimbursement does not provide reimbursement for vaccine.
  - Administration of vaccine under Current Procedural Terminology code 90471 (immunization administration) and code 90736 (zoster [shingles] vaccine; live, subcultaneous injection).
  - If Medicare is a primary insurer, vaccine must be submitted under Medicare Part D, and patient must meet deductible and copay requirements of Medicare-approved provider.

- **Vaccine Availability**
  - Availability may be limited because both herpes zoster vaccine and varicella virus vaccine are produced from same varicella-zoster virus strain.
  - High demand for both vaccines may delay shipments.
reimbursement. Because administering the herpes zoster vaccine is not an urgent issue, the physician could obtain vaccination authorization for a patient from the Medicare Part D plan and then administer the vaccine at the patient’s next office visit or physical examination. Sample precertification letters are available at http://www.vaccinesupportservices.com.

Many Part D plans participate in the eDispense program. The eDispense Medicare Part D Vaccine Manager is a Web-based option for processing in-office Medicare Part D Vaccine claims electronically. When using the eDispense program, you must accept the Part D plan’s reimbursement amount, which includes the enrollee’s co-payment as payment in full for the vaccine product charge and administration. The provider collects any co-payments and deductibles. To enroll, visit http://enroll.edispense.com.

Another option regarding reimbursement is to have the patient first obtain the vaccine from an authorized pharmacy, and then receive the actual vaccination at either the authorized pharmacy or the physician’s office. Additional vaccination support information may be accessed at https://www.merckvaccines.com/zostavaxProductPage_frmst.html.

Information for patients between the ages of 60 and 64 years on obtaining vaccine reimbursement for specific insurance plans in particular states can be accessed at http://www.vaccinesupportservices.com/reimbursement-forms/health-plan-info.aspx.

The amount of reimbursement for the herpes zoster vaccine varies from state to state. A review of commercial insurance plans and Medicaid reimbursement in Michigan show payments in the range of $7 to $28 for immunization administration (CPT code 90471).

Vaccine Availability and Shipment
The availability of the herpes zoster vaccine has been limited at times as a result of the fact that both the herpes zoster vaccine and the varicella virus vaccine are both produced from the same VZV strain. High demand for both vaccines has caused some delayed shipments of the zoster vaccine.

Vaccine supply and shipment schedules may be accessed at: https://www.merckvaccines.com/srv/gw/home/desktop.jsp?frame=1.

Comment
The value of herpes zoster vaccine administration is demonstrated by statistics of vaccine efficacy for reduced zoster incidence and burden of illness. Although efficacy results for patients older than 70 years were not as statistically impressive as results for younger patients, the absolute benefit of vaccination for these older patients may still be substantial considering the increased incidence of herpes zoster and the greater severity of illness in this age group.

As with all patients in the geriatric setting—including those residing in continuing care retirement communities, assisted living facilities, or skilled nursing facilities—the risk-vs-benefit ratios of all herpes zoster treatments should be evaluated for each patient. The cost of the herpes zoster vaccine for disease prevention may be negligible compared with the costs of medications needed for the long-term management of the disease and its complications, including pain and disability associated with PHN, which may persist for many years.

The pathologic development and complications of herpes zoster, the difficulties associated with drug treatment, and the availability of vaccination all underscore the importance of overcoming barriers to immunization and increasing vaccine uptake, as further described elsewhere in this supplement to JAOA—The Journal of the American Osteopathic Association. Achieving this goal is especially important in the elderly population, in whom treatment is the most difficult and complications are the most debilitating.

References