

September 4, 2014

Marilyn Tavenner
Administrator
Centers for Medicare and Medicaid Services
200 Independence Ave., SW
Washington, DC 20201

Dear Administrator Tavenner:

Last month, the Advisory Committee on Immunization Practices (ACIP) took the rare step of holding an off-cycle meeting to ensure reconsideration of recommendations related to the 13-valent pneumococcal conjugate vaccine (PCV13). The Committee wanted to ensure updated recommendations were in place in time for this year's flu season. Their urgency to re-examine the scope of use for the vaccine demonstrates the need to ensure access to the vaccine by seniors and other at-risk populations during this year's flu season. We are writing to urge the Centers for Medicare and Medicaid Services to use its authority to expedite an update to the manual instructions to reflect the new ACIP recommendations when they are finalized in this month. CMS has the ability to ensure timely access to the vaccine and we see no reason to delay.

Pneumonia is a serious respiratory infection that is a leading cause of death throughout the world. In the United States and Europe, pneumonia caused by the bacterium *Streptococcus pneumoniae* (pneumococcus) is the most common form of community-acquired bacterial pneumonia. The adult mortality rate for this type of pneumonia averages between 10 percent and 20 percent, and may exceed 50 percent in high-risk groups worldwide. About 900,000 Americans get pneumococcal pneumonia each year, nearly half of whom end up in the hospital. Among adults 50 years of age and older, there are approximately 440,000 cases of pneumococcal pneumonia each year in the United States, with approximately 25,000 pneumococcal disease-related deaths annually.

There is a synergistic relationship between viral influenza and pneumococcal disease, which makes flu season a critical time for adults to be vaccinated with pneumococcal vaccine. Previously, ACIP had recommended that PCV13 only be given to certain very high risk populations. Last month, they determined that routine use of the vaccine can help protect adults aged 65 years and older against pneumococcal disease. Specifically, the ACIP voted to recommend the following:

1. Adults 65 years of age or older who have not previously received pneumococcal vaccine or whose previous vaccination history is unknown should receive a dose of PCV13 first, followed by a dose of PPSV23.
2. Adults 65 years of age or older who have not previously received PCV13 and who have previously received one or more doses of PPSV23 should receive a dose of PCV13.
3. The recommendations for routine PCV13 use among adults 65 years and older* should be re-evaluated in 2018 and revised as needed.

There are 25 million patients in Medicare, including approximately 13 million at risk and high risk individuals who, according to the new recommendations, should receive a follow-up dose of PCV13. They will not have access to PCV13 this flu season because they have previously been vaccinated and CMS's current policy is to only cover one pneumococcal vaccine in a lifetime. If this is not amended on an expedited basis, these patients will have to wait until after the peak of this flu

season to have access to the new vaccine. Moreover, a delay in updates until January of 2016 will cause further issues during next year's flu season. CMS can and should issue updated guidance on fee schedules, guidelines, coverage and reimbursement processes for PCV13 before this coming flu season. The evidence of benefit to patients was present enough to spur action by ACIP, and CMS has implemented expedited coding and payment in the past, such as for the H1N1 vaccine. We urge you to use your authority to issue new policy soon so Medicare beneficiaries have access to the vaccine this year.

Sincerely,

AARP

Academy of Nutrition and Dietetics

Alliance for Aging Research

American Academy of Family Physicians

American Academy of Osteopathy

American Autoimmune Related Diseases Association

American College of Osteopathic Family Physicians

American Lung Association

Caregiver Action Network

Gerontological Society of America, convener of the National Adult Vaccination Program

Infectious Disease Society of America

National Aging in Place Council

National Association of Chain Drug Stores

National Association of Nutrition and Aging Services Programs

National Council on Aging

National Foundation for Infectious Diseases

National Silver Haired Congress

RetireSafe