

Streptococcus Pneumoniae Conjugate Vaccine Managed Care Advisory Panel Recommendations on PnC7 and Vaccine Reimbursement Guidelines

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The *Streptococcus pneumoniae* Conjugate Vaccine Managed Care Advisory Panel comprised pediatricians, medical directors, pediatric nurses, and pharmacy directors involved in many aspects of managed care. As noted by the panel's discussion leader, F. Randy Vogenberg, RPh, PhD, Institute for Integrated Healthcare, the members represented the breadth and variability of current managed care.

Advisory Panel Objectives

The goal of the advisory panel was to identify reimbursement and implementation issues surrounding the vaccine in children ages 0 to 5 years, based on the rationale, epidemiology, efficacy, cost-effectiveness, and estimated public health effect data they heard over the course of the meeting and their individual experiences in managed care organizations.

Consensus

Using the data from the presentations, the panel members evaluated the implementation and reimbursement possibilities surrounding 2 scenarios of likely recommendations

from the American Academy of Pediatrics (AAP) and the Advisory Committee on Immunization Practices (ACIP) for the vaccine, as described in the Table. Possible recommendations from the American Academy of Family Physicians (AAFP) were also discussed. From these activities a consensus was developed. The main points are as follows:

1. The vaccine is significant and important, and should be incorporated into the practice of preventive medicine for children.

The major clinical issues surrounding pneumococcal disease are resistant organisms and severe morbidity and mortality. The panel unanimously agreed that the clinical efficacy data, particularly in terms of invasive disease, are impressive. The data clearly show that the burden of disease can be affected by the series of shots given by age 2 years. The data also show that the immune response falls off quickly after the third shot, and experience with other vaccines indicates that the fourth shot is useful to maintain long-term immunity. Additional data on immune response

in older children is needed and should be available around the time of the vaccine launch.

According to some panel members, a secondary benefit of the vaccine—both medically and economically—will be the change in physicians' attitudes and approaches to a febrile 6- to 36-month-old child. For example, the *Haemophilus influenzae type B* (Hib) vaccine brought much relief to physicians regarding the risk of meningitis, so lumbar punctures were no longer deemed necessary in most Hib-immunized children. Similarly, some panel members indicated that PnC7 will bring comparable paradigm shifts once it is used widely and physicians become comfortable with its efficacy. Febrile toddlers and young children will not require office visits and aggressive work ups (eg, blood counts, blood cultures, and first-line ceftriaxone use) if they have been fully immunized with PnC7, unless they appear clinically ill or toxic, thus theoretically reducing personnel, laboratory, and medication costs for managed care organizations (MCOs).

2. Adequate reimbursement will affect providers' use of the vaccine.

The largest hurdle to vaccine implementation will be the level and timing of reimbursement (which is driven by acquisition cost). The relationship between vaccine use and acquisition cost, however, is a function of the compensation practices of MCOs.

The major clinical issues are penicillin-resistant organisms, severe disease, and otitis media. The order of importance varies with the target audience. For "academicians" (ie, those in the healthcare industry outside of clinical practice), penicillin-resistant *S. pneumoniae* (PRSP), severe disease, and otitis media (OM) are ranked in decreasing order of importance. For MCOs, the major issue is OM because of the potential cost savings with PnC7, followed by severe disease and PRSP. For practic-

ing clinicians, however, OM and severe disease both occupy first place as the major clinical issues.

Although clinicians are interested in clinical value, adequate and timely reimbursement will influence their practice behavior. The rationale is that by the time the recommendations are published, a professional organization, such as AAP, ACIP, or AAFP, will have examined the clinical value, so the remaining issue is cost.

Physicians will need to prepare for changes in their office finances to cover the vaccine. Capitated physicians may face a financial impasse because they may not be given additional money for the vaccine. As a result, these providers will need to be further convinced of the value of this vaccine.

From a medical-legal perspective, physicians should also consider what is best for the child, including awareness of the social issues/sequelae of pneumococcal diseases outside of the 15-month immunization window and the serious public health risk of antibiotic overuse.

Those in fee-for-service plans will need to pay for the vaccine up front. The pharmaceutical company manufacturing the vaccine will need to consider options to delay payment from

Table. Vaccine Recommendation Scenarios

<p>Scenario 1 The ACIP has given the recommendation to routinely immunize all children at 2, 4, and 6 months of age, with a booster dose at 12 to 15 months. Catch-up immunizations are recommended for all children up to 59 months of age. For children 2 years of age or older, only a single dose is required. The AAP provides the same recommendation only for the infant series. However, the ACIP uses wording saying that the financial implications of use can be reconciled prior to use.</p> <p>Scenario 2 The ACIP has given the recommendation to routinely immunize all children at 2, 4, and 6 months of age, with a booster dose at 12 to 15 months. Catch-up immunizations are recommended for all children up to 36 months of age. For children 2 years of age or older, only a single dose is required. The AAP provides the same recommendation.</p>

the providers for the vaccine to facilitate usage. For example, during a 6-month grace period, MCOs could approve the vaccine and provide reimbursement to those physicians. Reimbursement will also become very important for catch-up immunization if it is not universally recommended.

The panel noted that adding to the number of shots currently administered per visit may become an issue and that a combination vaccine will improve utilization. Doctors and nurses will be less likely than parents to accept multiple vaccine shots at one visit. Many panel members thought that if the health benefits were explained to the parent, the fear of multiple shots often would be overcome. One study showed that health-care providers are often poor predictors of parents' acceptance of multiple shots.¹ As seen in the vaccine efficacy study, where as many as 5 shots were given on 1 visit, parents willingly accepted what was in the best interest of the child.²

However if the vaccines are not reimbursed, families may be less willing to get the vaccine. One panel member suggested that if the vaccine is not reimbursed initially, families should be encouraged to keep their receipts and ask for repayment after it is approved by the MCO.

In some respects, the amount of care delivered may also be member driven (ie, parents must actually take the children to the doctor's office to get the vaccine, just as they would for other vaccines). The panel felt that if the ACIP/AAP/AAFP recommended the vaccine states would most likely support those recommendations and daycare centers would be constrained to follow state recommendations, thus promoting further member-driven immunizations.

3. Approval of payment is driven by the professional recommendations.

All panel members agreed that if the vaccine were recommended by

the key professional organizations (ACIP, AAP, and AAFP), they would cover it, most likely as a medical benefit. If the AAP and AAFP recommendations are different from those of the ACIP, some panel members said their plan will use the ACIP recommendations but physicians may choose to follow their own professional organization's recommendations (eg, a pediatrician will follow the AAP recommendations). ACIP, AAFP, and AAP will most likely have the same recommendations but the language in the AAP and/or AAFP statements may be less strict to allow for financial flexibility.

Another stimulus for MCO approval and reimbursement will be the likely inclusion of PnC7 in assessments of MCOs by the National Committee for Quality Assurance in the Health Plan Employer Data and Information Set (HEDIS). PnC7 will most likely be included in HEDIS if it is recommended by the ACIP, however, several panel members noted that HEDIS may not measure catch-up immunizations.

If the ACIP, AAFP, and/or AAP recommend the vaccine, the panel agreed that cost-benefit discussions will provide objective evidence that can be an important supportive element of the decision-making process, particularly for chief financial officers in MCOs when determining the budget impact. For most employers, cost-benefit discussions are not necessary, except to self-insured employers for whom these discussions only soften the impact of the cost. Self-insured employers may feel pressured to offer the vaccine in their benefits packages because of possible liability problems. Professional recommendations will ultimately drive MCO coverage of the vaccine, but if the vaccine is too expensive, cost benefit will be a more significant concern. Also, packaging, delivery, and storage costs may negatively impact administrative costs.

Many MCOs are likely to reimburse the vaccine for a child older than 36 months with recurrent OM and in daycare, but they will probably not proactively recommend it. This is also true for catch-up shots in those children older than 36 months. If it is not recommended, the panel does not expect a high volume of vaccinations. There is no need to target risk groups because they are covered under the recommendations as outlined in the AAP/AAFP/ACIP scenarios.

4. Continued outcome studies should be incorporated into the vaccine program. These studies should be based on a uniform data collection set with a commonly agreed upon definition.

Physicians and MCOs will want to know the long-term efficacy of the vaccine and look for possible replacement with other serotypes. These results may affect future routine immunization and catch-up policies.

Surveillance is also important because children carry more than one serotype at a time, and nasopharyngeal carriage rates of pneumococcus can reach up to 60% in preschool children.³ Although nasopharyngeal carriage does not necessarily imply invasive disease, acquisition of a new serotype does predispose to invasive disease within 1 month.⁴ However, surveillance should go beyond serotype tracking and include epidemiologic studies on the incidence of OM episodes or visits and bacteremia in the childhood population.

Surveillance will not be performed immediately because achieving full use will take time.

It was recommended that the studies be undertaken up to 5 years after the last vaccine dose is given. However, accurate tracking will remain a significant barrier. For example, capitated physicians have no incentive for filling out account forms. Auditing may increase tracking but

the feasibility and expense of audits make it questionable. Some MCOs may choose to audit their physicians anyway to ensure proper implementation of the vaccine. Also, OM has to be considered separately when tracking efficacy because the nasopharynx can never be sterilized. Therefore, OM may still be present due to other causes.

Conclusions

The efficacy data clearly support the use of PnC7 in preventive pediatric medicine practices because of its effect on burden of disease. It is expected that the use of PnC7 in pediatric medicine, however, will be affected by MCOs' reimbursement policies.

Reimbursement for the vaccine will be determined by recommendations from the ACIP, AAP, and AAFP. If it is recommended by these organizations as is expected, MCOs will cover the vaccine. Inclusion of PnC7 in HEDIS assessments will also promote MCO reimbursement. Given the important health benefits, MCOs should promptly and adequately reimburse providers for the vaccine.

Continued surveillance of outcomes and serotypes, incorporated into the vaccination program, would be helpful to measure the long-term impact of antibiotic-resistant serotypes and a potential herd effect. Also, tracking repeat visits for OM and PE-tube placement would not be difficult to audit; those data may also act as markers for vaccine efficacy in the otitis-prone population.

PnC7 has demonstrated outstanding clinical results. It has a significant impact on invasive disease, which is expected to have a significant public health effect.

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