MANAGED CARE AND SPECIALTY PHARMACY IMPLICATIONS OF RSV MANAGEMENT*

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ABSTRACT

Respiratory syncytial virus (RSV) is the leading cause of hospitalization among children aged younger than 2 years, responsible for 75,000 to 125,000 pediatric hospitalizations a year at an estimated cost of $12,000 per hospitalization. With no widely available, long-term immunization for RSV or standard treatment protocol, preventing infection in high-risk infants through immunoprophylaxis with the humanized monoclonal antibody palivizumab is an important component of managed care efforts to reduce the morbidity, mortality, and costs associated with this common childhood disease. Most managed care plans incorporate guidelines from the American Academy of Pediatrics into their coverage and require preauthorization. This article highlights the role of preauthorization in RSV immunoprophylaxis and the role that specialty pharmacy can play.


Respiratory syncytial virus (RSV) is the leading cause of hospitalization among children aged younger than 2 years, and is responsible for 75,000 to 125,000 pediatric hospitalizations a year at an estimated cost of $12,000 per hospitalization.1 Given that there is no widely available, long-term immunization for RSV, nor any standard treatment protocol, preventing infection in high-risk infants forms the centerpiece of managed care efforts to reduce the morbidity, mortality, and costs associated with this common childhood disease.2 Immunoprophylaxis with the humanized monoclonal antibody palivizumab is an important component of that effort. Current recommendations call for 3- to 5-monthly doses of palivizumab for certain pediatric subpopulations.2 Given the average cost of $5000 for a 5-course series, it is important that managed care organizations (MCOs) implement criteria to ensure that the most appropriate patients receive immunoprophylaxis.

The majority of MCOs incorporate the most recent guidelines from the Infectious Disease Committee of the American Association of Pediatrics (AAP) into their immunoprophylaxis protocols. Issues that MCOs face in developing their own guidelines include whether the drug is covered under the medical benefit (because it is an injection usually administered by a healthcare professional) or under the pharmacy benefit, and, if the latter, on which tier. The difference is important in terms of co-payments for the patient.

Plans also should communicate guidelines for the use of immunoprophylaxis to the appropriate providers, primarily pediatricians, and neonatologists. Other issues that should be addressed include:

- Monitoring the beginning and duration of RSV season to ensure prophylaxis begins and ends when it is most effective.
• Determining the gestational age of infants to identify immunoprophylaxis candidates and confirm coverage eligibility
• Determining approved places of service (ie, if home health should be utilized to provide home-based services)
• Assessing any underlying medical conditions as addressed in the AAP guidelines

The high cost of palivizumab makes it an ideal candidate for prior authorization (PA). Indeed, an estimated 81% of health plans surveyed in late 2008 indicated they required such authorization. The Table depicts the PA criteria for one such plan based on the 2009 recommendations from the AAP. That plan, SelectHealth, is a 500,000-member health plan based in Salt Lake City, UT.

It recently reported on the outcomes from 3 RSV seasons, during which the plan received 1,090 PA requests for palivizumab. It approved 742 (68.1%) and denied 348 (31.9%). The mean gestational age for the approved group was 32.5 weeks compared to 34.4 weeks in the denied group (P < .001). Of the infants denied coverage, 5 (1.4%) had a documented RSV-related emergency department (ED) visit, 4 of whom had a subsequent inpatient stay, and 14 (4%) had an RSV-related hospital stay.

Of the 629 infants who received palivizumab, 14 (2.2%) had an ED visit, 12 of whom were subsequently hospitalized, and 40 (6.4%) were hospitalized for an RSV-related diagnosis. One infant died of respiratory failure. The study also showed that ED visits were significantly lower in the PA-denied group (1.4% vs 2.2%, P = .019) as were per-infant hospital costs and total costs ($210.23 vs $822.60 [P = .015] and $222.56 vs $8533.82 [P = .002], respectively). The study identified drug-avoidance costs of $2.4 million because of the PA program over the 3 seasons.

The authors suggested that the increasing rate of RSV-related hospitalizations since the 1980s as well as the higher proportion of children-per-family in Utah, where the study was conducted, could be responsible for the higher hospitalization rate in the PA-approved group, as well as the fact that the PA-denied group would, by definition, be healthier.

The results of this study show that the use of PA can be cost effective for health plans. Health plans should remain vigilant in developing PA programs that are evidence based and result in quality improvement.

### Speciality Pharmacy Considerations with RSV Immunoprophylaxis

Specialty pharmacy is growing at a rapid pace in the United States, fueled by demand from payers for cost control and utilization management over the equally fast-growing area of high-cost, specialty pharmaceutical drugs. Nationally, specialty pharmacies, including those owned by MCOs, manage approximately 40% of spending on specialty pharmaceutical drugs.

A growing number of MCOs have turned to specialty pharmacies to provide access to the RSV immunoprophylaxis drug palivizumab as well as utilization management services. The pharmacies can provide numerous services ranging from simply providing the drug to physicians and patients to managing utilization, tracking compliance, providing disease management services, and communicating with patients and their families.

For instance, representatives from a specialty pharmacy may call families the day before an appointment for an injection to remind them of the appointment, then contact the physician.

### Table. SelectHealth Prior Authorization Criteria for Use of Palivizumab

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<td>1. Less than 2 y of age with CLD requiring medical therapy (such as supplemental oxygen, bronchodilator, diuretic, or corticosteroid therapy) within 6 mo before start of RSV season, or the infant has hemodynamically significant CHD</td>
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<td>2. Infants born less than or equal to 32 wk of gestation with or without CLD</td>
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<td>a. Major risk factors: gestational age and chronologic age at start of season</td>
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<td>b. Born less than 28 wk gestational age and &lt;12 mo of age</td>
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<td>c. Born 29–32 wk gestational age and &lt;6 mo of age before start of RSV season</td>
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<td>3. Infants born between 32-35 wk gestational age and &lt;6 mo old at start of RSV season with ≥2 risk factors:</td>
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<td>a. Day care attendance</td>
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<td>b. School-aged siblings</td>
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<td>c. Exposure to environmental pollutants (including secondhand smoke)</td>
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office the day after the appointment to ensure the patient received the dose. The specialty plan also may provide PA services; align patient care coordinators with groups of patients to ensure adherence; provide member-level data to the plan; and assist families with accessing manufacturer payment assistance programs.

Horizon Blue Cross Blue Shield of New Jersey implemented a specialty pharmacy management program in 2002 to deliver palivizumab in a “cost-effective and coordinated manner.” The plan reported a savings of $803,250 through avoidance of inappropriate utilization, as well as a savings of $1.3 million for the prescriptions that were filled given the deeper discount the plan secured from the specialty provider. The pharmacy reported 99.4% compliance with the injection series, and minimized waste by ensuring that the appropriate-sized vial (100 mg or 50 mg) was used.

Specialty pharmacies also can partner with home care agencies to provide injections in patients’ homes. Approximately 70% of patients under the Walgreens Specialty Pharmacy palivizumab programs receive their injections in this manner. Studies find such programs can improve compliance. For instance, one study from the Palivizumab Outcomes Registry found that infants who received the prophylaxis at home \((n = 1226)\) were significantly more compliant than those who received it in a clinic or office \((n = 17,641)\) both in terms of the number of doses received \((88\% \text{ vs } 81\%, P < .0001)\) and timing of the doses \((73\% \text{ vs } 66\%, P < .0001)\). Infants who received home-based injections also had fewer RSV-related hospitalizations \((0.4\% \text{ vs } 1.2\%\) \(P = .0139)\).

Most specialty pharmacies also base discharge planners at area hospitals who could work with neonatologists and neonatal intensive care unit nurses to coordinate post-discharge administration of prophylaxis and avoid administration in the hospital, where it may be more expensive. Discharge planners also could ensure that the infant is added to the parents’ health plan or Medicaid within the first 30 days after birth.

CONCLUSIONS

The high cost of RSV immunoprophylaxis requires careful management of its utilization. MCOs have a variety of tools available to improve utilization and compliance, including PA, home administration, and specialty pharmacy management.

DISCUSSION

Dr Rich: As Doug mentioned earlier, it is very important once we identify the patient that he or she stay on the therapy. We need to look at this issue of prevention cost versus treatment cost, and monitor how many injections the patient has had. It would be very unusual for us to ship more than 1 injection to the patient at a time. Some therapies we can send more, but RSV prophylaxis is clearly a candidate for 1 injection sent at a time.

Then we have to make a determination about how we are going to get that product to the member. Do we use specialty pharmacy? Is it all specialty pharmacy providers or is it specific specialty pharmacy providers? Some manufacturers only make products available through a certain subgroup of specialty pharmacy providers. If the plan contracts with one of those specialty pharmacy providers, it is probably not a big issue, but if they do not, it becomes a very big issue because now you may have to open up contract negotiations with that specialty pharmacy provider when you may not have had a relationship with them previously.

Mr Calla: I will comment at this point because we are discussing distribution. The current model for palivizumab is they have approximately 30 to 35 “authorized providers” of the product at this point. Of those, the top 4 or 5 really do the bulk of dispensing. And in health plans, typically what we are seeing is most health plans go to 1 or 2 providers of product. Some will go with a single provider. Others will go with 2. Occasionally you will see some with 3 providers but they are limiting the amount of providers they want to work with.

A big part of the reason for that is that when you are down to 2 or 3 providers you can get the data more efficiently. You have definitely got more monitoring capability over your distribution channel and compliance because then you are having regular communication with your providers.

Dr Rich: That makes sense. I know one of my first experiences with a restricted provider was with the first drug available for infusion for pulmonary arterial hypertension. It was only available from 1 provider and I did not have a contract with that provider. Here comes a request. What do you do with it? Now you have got to go out and try to immediately negotiate a contract with a provider. You have no relationship whatsoever and no negotiating leverage. It is not the
case with this category of drugs, of course, but, yes, that becomes an issue.

**Dr Burgoyne:** Nick, you have talked about the coordination when you have a new patient on service; how do you coordinate between the health plan, the physician, and the patient?

**Mr Calla:** Well, you have a brand new baby who comes into service. So you have the patient care coordinator and the insurance specialist making sure the guidelines are being adhered to for that particular plan. Then the referral comes in, the insurance is verified, making sure if prior authorization is required, it is done. The patient is contacted so they know where we are in the process and when the referral comes in from the doctor, we also acknowledge that.

Then the patient care coordinator calls the patient and makes sure the patient understands what will happen and when the dose will be delivered either to them or the doctor.

We deal with the manufacturer at different levels. From a national accounts perspective, it is typically a quarterly business-type review. During the heart of the season, we have a trained account manager contact the manufacturer on almost a daily basis.

**Dr Lee:** Do you see any way that the specialty pharmacies and maybe even the managed care programs can help the individual hospitals manage this better with infants who are in the hospital for 2 or 3 months?

**Mr Calla:** We typically have discharge planners at many of the major hospitals around the country. Often these discharge planners are working, for example, with transplant patients to coordinate the discharge and make sure they get the right products as they leave the hospital. Oncology is another area where we do a lot of coordination. I would think that RSV could fit in there in working with the discharge planners.

**Dr Rich:** Yes, I think it would be very similar because you would think the discharge planner at the hospital would get involved right away with the case manager of the managed care plan. I really think they would have to have some care management for these patients from the beginning. Also, it is an enrollment issue. I am assuming one way the plan gets that information is the hospital calling saying, “We’ve got a baby born to the plan.” So that goes to enrollment and they take it from there.

But it goes to the further level of when the baby is ready to be discharged and once they get the dose, which is probably the more germane issue here.

**Dr Buckley:** Yes. I do not know how open your contracting is. I know you said maybe some states have restrictions but we operate under different contracts with facilities. And some do get paid for those services.

**Dr Rich:** There is also a big issue from the Medicaid perspective that when a woman becomes pregnant she goes up to a higher level of income available to get on Medicaid coverage. Then after the birth there is a certain period of time when the baby could be kept on coverage but the mother may not be. And if they are a managed Medicaid plan, there are differences in how that works, as well.

**Mr Calla:** Yes, they all have their nuances. We see that from the specialty pharmacy point of view because we are dealing with multiple plans. That is why you have to have the insurance verifiers and the benefits specialists in place because every plan has its nuances.

**Dr Rich:** I am assuming that for uninsured patients the manufacturer has some type of patient assistance program to offset cost of drug.

**Mr Calla:** Yes, there is. What typically happens is we go to the manufacturer first to establish these programs to help pay the co-pays on these particular programs. If the income criteria do not work out, then we will go to some of the foundations around the country or locally to look for funding. So again, it really comes down to just having the infrastructure in place to make this happen because none of this is especially difficult but it is time consuming and it can get convoluted.

That is really where the health plans are recognizing the value of specialty pharmacy. In fact, specialty pharmacy was developed for all the reasons that we are talking about here: to be able to work with these complicated disease states. When you look at the retail pharmacists, they are generalists, they are a mile wide but an inch deep. And the converse is true in specialty pharmacy where you are dealing with a much narrower set of drugs, but you go very deep into that from a reimbursement patient management point of view.

**REFERENCES**


2. Committee on Infectious Diseases. From the American Academy of Pediatrics: Policy statements-modified recom-


