

Update on Outpatient Parenteral Antimicrobial Therapy



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Outpatient parenteral antimicrobial therapy (OPAT) itself is not a new concept in health care. Intramuscular penicillin has been used in ambulatory care since the 1950s. The administration of intravenous (IV) antibiotics in the outpatient setting was introduced in the United

States more than a quarter of a century ago and is currently available in most communities in one form or another. The primary delivery model is that of home infusion or home health, in which services and products are delivered directly to patients in their homes. Ambulatory infusion centers have also been developed based in physician offices or hospitals or as a freestanding part of a home infusion-provider program.

The excitement of starting an OPAT program, however, and the assurance of success have faded in light of devel-

Factors to consider in outpatient parenteral antimicrobial therapy (OPAT) include a changing patient population, standardized care guidelines, recent research outcomes, once-daily antibiotic use, the administration of oral versus intravenous (IV) therapy and switching from one to the other, the controversial use of an "IV push," infection control, reimbursement, and legal issues. This article addresses all of these factors, with a close look at the drugs being used in OPAT and the final regulations of the Federal Physician Self-Referral Statute.

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opments over the past few years. Payers do not always appreciate the cost savings afforded by treating persons with IV therapy outside the acute care hospital setting. Instead, they expect it, and often contract with providers to share the major portion of risk in the cost of delivering care. Net returns have

decreased due to reduced payments, and managed care penetration has created an environment in which pre-authorization, preferred provider status, and often exclusive contracts are required of providers to offer services to most of their referrals.

Despite these discouraging developments, the industry has continued to grow, and an average of at least one in 1000 Americans continues to get a course of OPAT every year.¹ There have been tremendous strides with the introduction of new drugs, infusion pumps, and venous access devices specifically designed to support cost-efficient, safe, and convenient delivery.

CHANGING PATIENT POPULATIONS

Changes in the population of patients treated with OPAT have been ongoing. At first, referrals were made most often by infectious diseases specialists for the treatment of endocarditis, osteomyelitis, and infections that require long courses of therapy extending beyond the need for hospitalization.^{2,3} With time and experience, other

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physicians began referring patients for OPAT, and shorter courses were provided for a wider variety of problems such as respiratory infections, cellulitis, wounds, and pyelonephritis.^{4,6}

Provision of OPAT for persons with AIDS was a mainstay of many programs 10 years ago. IV ganciclovir, foscarnet, and didanosine were used for the treatment

and suppression of cytomegalovirus, often as lifetime therapy. Amphotericin B and pentamidine, as well as other antimicrobials, were frequently needed to treat the other opportunistic infections common in this population. However, highly active antiretroviral therapy brought dramatic changes, with marked declines in the number of individuals with cytomegalovirus or serious fungal infections. A high percentage of those with HIV are now managed as chronic-disease-state patients, rarely developing complex infections, and treated most often with a variety of oral rather than IV medications.

Clearly, this is a dynamic and relatively young market. It is important to keep abreast of new developments and changes in it, as well as in medicine in general, that may have an impact on the industry as a whole, providers of OPAT, and patients on OPAT. Given the rapid changes that have already occurred, it may be equally important not to remain wedded to models, patient populations, and systems that may become quickly outdated.

CLINICAL GUIDELINES

Entrepreneurial pharmacists, physicians, and nurses were the primary drivers who brought OPAT (and home infusion therapy in general) to the market. Providers of this new, and

TABLE I
Useful Websites

- IDSA guidelines for community-based parenteral antimicrobial therapy: www.idsociety.org. The IDSA is rewriting these and welcomes input: alantice@idlinks.com.
- OPAT Outcomes Registry: www.opat.com
- Missouri Alliance for Home Care: www.homecaremissouri.org
- National Home Infusion Association: www.nhianet.org
- Final Stark II Regulations: www.access.gpo.gov. Click on GPO Access, then Federal Register. Locate the Table of Contents for 2001, the date January 4, 2001, and the Health Care Financing Administration Section, Medicare and Medicaid. Choose PDF or text for selection 855-904.

IDSA = Infectious Diseases Society of America; OPAT = outpatient parenteral antimicrobial therapy.

almost immediately successful, model were left to define standards and methods for care, often quite different from those developed for the hospital setting or traditional home health. Few, if any, pre- and postimplementation studies were conducted to determine how best to deliver OPAT in terms of safety or efficiency or within any guidelines.

Managed care has initiated a demand for more standardized care guidelines in all settings, and OPAT is no exception. Although many of the guidelines developed are proprietary, professional medical societies have published standards of care within their realm of expertise in peer-reviewed medical journals. It is important for providers to be aware of published guidelines that are available for the therapies they provide, as well as for OPAT in general.

The Infectious Diseases Society of America (IDSA) published guidelines for community-based parenteral antimicrobial therapy in 1997 and posted them on its website (Table I).⁷ These guidelines outline the minimal criteria for a quality program, the role of the team members, appropriate infections to treat, and patient monitoring needed. Guidelines have also been written for Canada and the United Kingdom.^{8,9} The IDSA has recently undertaken the task of rewriting its guidelines and welcomes input from anyone involved with OPAT (Table I).

OUTCOMES RESEARCH

Collection, analysis, and reporting of outcomes data are the goals for the measurement of quality in health care, as well as the method for identification of best practices and treatment modalities. OPAT provides an ideal platform for

well-studied.^{26,27} There may also be a legal risk involved because the FDA has not approved a drug for IV-push administration. Although some descriptive studies have been published, they tend to report the frequency of easily measurable outcomes only, such as phlebitis or a negative patient response.²⁸ What is not addressed are the potential systemic complications or any effect on the efficacy of the drug that might be related to a rapid infusion.

Another issue to consider is that reimbursement for an infusion is often quite different from payment for an injection of a drug. One could argue that clinical monitoring, venous access device maintenance, and patient education and support remain the same regardless of administration method. However, supplies, time, and the complexity of the procedure itself are often the factors payers take into account when determining fee schedules.

INFECTION CONTROL

In the past, infection control practitioners tried to apply hospital standards to the home, but this was impractical and not appropriate. The home or outpatient clinic setting is a much more controlled environment with regard to the risk of infection. There is clearly less exposure to antibiotic-resistant organisms and people with infections. Patients are also more cognizant, aware, and likely to ensure procedures are performed consistently. At the same time, a person's home or an outpatient clinic is not always the easiest environment in which to set up some practices common in hospitals, such as isolation.

OPAT Registry data demonstrate that "nosohusial" infections (contracted in the course of home care) appear to occur in only 1% or 2% of patients, whereas nosocomial infections occur in 5% of hospital admissions and increase in probability with each day of hospitalization.²⁹ Antibiotic-resistant organisms also appear to be more likely in the hospital. Several textbooks have addressed this issue from a new perspective, and the Association for Practitioners in Infection Control will address it with new recommendations for practical infection control measures for home care.³⁰⁻³²

REIMBURSEMENT

Policies and fee schedules with regard to reimbursement for OPAT continue to vary widely among commercial payers. The predominant model remains the "per diem" rate, which usually is a global daily fee for all OPAT services and supplies, with the drug negotiated and paid separately. However, the definition of what is included in the per diem fee varies widely, and some fees may be prorated based on dosing frequency or the age of the patient. Some payers still expect an itemized claim to be submitted, in particular from the ambulatory infusion program providers, such as physician offices. In 2000, several temporary "S" codes were assigned by the Health Care Financing Administration (HCFA), now known as the Centers for Medicare and Medicaid Services (CMS), to describe home infusion therapy per diems and nursing, as well as insertion of a peripherally inserted, central or midline catheter.³³ Prior to this, there were no HCFA/CMS common procedure coding system codes to accurately describe many of the supplies and services provided in OPAT. The National Home Infusion Association has launched efforts to standardize home infusion therapy coding among payers, which would facilitate billing and collections tremendously.

The primary changes in reimbursement for OPAT have been mandated for Medicare and Medicaid, primarily due to the Balanced Budget Acts of 1996 and 1997. These pieces of legislation from Congress demand that HCFA/CMS cut costs significantly in Part B Medicare. An indirect result of this legislation was the deletion from the durable medical equipment (DME) benefit in 1996 of the only antibiotic covered by Medicare at home on a pump, vancomycin. More recent changes have involved the rate of reimbursement for drugs covered in the home under the DME benefit, as well as those covered when administered on-site in the physician office.

Drug reimbursement has always been linked to the average wholesale price (AWP), established and updated twice a year by the manufacturers. In the past, HCFA/CMS directed the DME resource centers and local Part B carri-

TABLE II
Federal Physician Self-Referral Statute (Stark II)

Interim Final Rule Highlights

- Direct supervision issues are not addressed, as previously suggested. Medicare coverage rules will continue as before without any changes. Note: The CPT 90780 for an infusion hour still requires direct physician supervision per Medicare coverage rules. Specific definitions and exceptions related to this can be adjudicated only through a local Medicare carrier or via HCFA-provider relations.
- The Final Rule does not prohibit physician dispensing and reimbursement for infusion pumps and/or prescription drugs covered by Medicare when used at home by the patient, although they fall under two of the prohibited designated health services categories. The only antimicrobials currently covered by Medicare at home are acyclovir, ganciclovir, foscarnet, and amphotericin. External infusion pumps must be nondisposable. The physician must become a DME provider and submit claims to the DMERC in order to be reimbursed by Medicare for these drugs and pumps. Note: Regulations do not expand Medicare coverage criteria. Rather, they will allow physician dispensing and reimbursement for these items used at home only if already covered. Remember that Phase I does not address this or any other exception with regard to Medicaid. This may be more restrictive, probably because most Medicaid programs already provide coverage for pumps and drugs used in the home, whereas Medicare covers only a select list under the DME benefit. Home enteral and parenteral nutrition, although covered by the same Medicare DME benefit under certain criteria, are still considered a prohibited referral.
- A couple of issues that were blurry under the proposed rule regarding drug and device manufacturers are clarified. Free drug samples from drug manufacturers will not constitute compensation. Drug and device manufacturers will not be considered "entities," which means that ordering a drug or device is not a prohibited referral to those manufacturers. Note: FDA regulations would still prohibit the physician from billing a patient or payer for free samples or accepting direct or indirect financial compensation from a manufacturer directly related to volume of prescriptions.
- The definition of *referral* is revised to clarify that any work or procedure performed personally or directly supervised by the billing physician is not considered. This means that when a physician provides supervised infusion to a patient from the office practice, even if a solo practitioner, he or she can bill the CPT 90780, and it will not be considered self-referral for prescription drugs. In-office infusion meets the group practice exception; also, if a physician actually provides the infusion personally in one's home (which is covered under Medicare), this clarification means that it would not be considered a prohibited referral.
- Physicians are under no obligation to pass on to Medicare manufacturer or distributor discounts for outpatient prescription drugs.
- An independent contractor physician, if certain requirements are met, is allowed to provide direct supervision (required by Medicare coverage criteria for CPT 90780). This would allow a part-time physician to be hired to supervise in-office infusions during weekends or other times and still meet the group practice in-office provision criteria.
- HCFA/CMS sees no plausible way for home health services, as one of the designated health services, to qualify for any exceptions. The bottom line on this is that a physician with an ownership or investment interest (including joint ventures) in a home health agency or home infusion provider organization will still be prohibited from making Medicare referrals to that entity (with some exceptions noted for publicly traded companies).
- Compensation rules, as opposed to ownership rules, have been relaxed in many areas, as long as certain criteria are met. Criteria are met if actual work is performed, the physician is paid at fair market value for it, and the compensation is in no way related to the volume of referrals made to the entity.
- Criteria are broadened under which payment methodologies and productivity bonuses are set up in a group practice that provides one of the designated health services.

CPT = current procedural terminology; HCFA = Health Care Financing Administration; DME = durable medical equipment; DMERC = durable medical equipment resource center; FDA = Food and Drug Administration; CMS = Centers for Medicare and Medicaid Services.

ers to reimburse at an average or mean of all the AWP's listed. Two years ago, this changed to 95% of AWP, and it remains the same. Carriers still have the flexibility to choose which AWP they use for which brand or packaging unit, and there are local cost adjustments; therefore a high degree of variability remains in reimbursement rates among states.

At some point during 2000, all state Medicaid carriers, as a group, determined through an independent study that the AWP was significantly and consistently higher than the actual acquisition cost borne by providers. They developed a database independent of prices set by manufacturers, intended to reflect more accurately average acquisition costs. This is now the basis for all Medicaid reimbursement for outpatient prescription drugs.

HCFA/CMS indicated it would direct carriers to reimburse providers based on acquisition cost, beginning with a list of 50 drugs on October 1, 2000. However, an emotional outcry from patients, physicians, nurses, and the home infusion industry resulted in the directive being rescinded until the end of 2001 at the earliest. The issue will no doubt resurface soon.

LEGAL ISSUES

There is now some litigation on the books with regard to OPAT, primarily related to monitoring for toxicities.⁷ This trend is likely to continue and makes quality assurance and careful documentation essential. The most common lawsuits concerning OPAT seem to be related to the vestibular and renal toxicity of gentamicin.

Regulatory changes that affect OPAT include increased demands and standards from the Occupational Safety and Health Administration for the use of needleless systems and other measures to protect health care workers from exposure to blood-borne pathogens (Table I). At a time when reimbursement has been ratcheted down considerably, any increase in overhead costs can be significant.

Phase I of the final regulations that interpret the Federal Physician Self-Referral Statute (otherwise known as Stark II) was finally published in the *Federal Register* on January

4, 2001 (Table I). The almost-two-inch-thick document includes summaries of all comments submitted (reported to be around 12,800) after the Proposed Rule was published in 1998, as well as the committee's response to those comments. Phase I covers about 85% of the rule, including HCFA/CMS's interpretation of the basic self-referral prohibition, the so-called global exceptions, selected compensation agreements, and the statutory definitions. Phase II will address ownership and investment exceptions, reporting requirements, and federal sanctions. It is important to note that no regulations regarding Medicaid were included in Phase I, but should be in Phase II.

The effective date for the regulations has been set as January 4, 2002. Highlights of the interim final rule that specifically affect physician office-based infusion therapy are listed in Table II.

Overall, the Interim Final Rules are favorable in terms of physician office-based infusion. The Stark regulations cover a wider range of issues than infusion, and physicians should assess their own situations on an individual basis. It is also important to note that the Anti-Kickback Statute and its defined safe harbors do still apply, that HCFA/CMS coverage criteria for Medicare are not affected, and that state laws may also dictate rules regarding physician referrals for commercial payer beneficiaries, as well as Medicare and Medicaid.

CONCLUSION

The environment for OPAT is changing and will undoubtedly continue to do so. The incentives for outpatient care will only grow with pressures for cost efficiency and with limited hospital resources. Nurses, pharmacists, physicians, and administrators need to work together for cost-efficient and safe care with OPAT. Patients are a remarkable resource that is often overlooked; they are eager to learn to take care of themselves so as to leave the hospital.

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