

**Medicare Part B Coverage for Home Infusion Drug Therapies
is Extremely Limited and
Is Not a Model for Part D Coverage**

Introduction

Medicare Part B coverage of home infusion drug therapy is quite limited. To the extent that home infusion drug therapies are covered under Medicare Part B, it is because coverage for a particular infusion drug therapy fits within the durable medical equipment (DME) benefit. Medicare Part B does not have a specific home infusion drug therapy benefit.

Thus, Medicare Part B coverage for home infusion drug therapy exists if (and only if) an infusion pump (an item of DME) is required and the Medicare regional carriers¹ recognize the particular therapy. The Medicare Modernization Act of 2003 (MMA), however, expands coverage for home infusion therapy beginning in 2006. The MMA provides that drugs that meet the criteria set forth in the newly-created Section 1860D-1(e) of the Social Security Act will be covered drugs under the new Part D benefit unless such drugs are otherwise payable under Part A or Part B. Since most infusion drugs that are prescribed and dispensed for home care are not payable under Part A or Part B, and since infusion drugs meet the Section 1860D-1(e) criteria, most infusion drug therapies available in the private sector will be covered under Part D.

In developing appropriate coverage criteria for home infusion therapy drugs under Part D, CMS should avoid using Part B as a model. The shoe-horning of these therapies into the DME benefit has resulted in overly limited coverage that is illogical and confusing. For example, the Medicare DME benefit does not explicitly recognize any professional services, despite the fact that specialized pharmacy and nursing services are essential to the safe and effective provision of home infusion therapies.

Instead, CMS should look to the private sector for guidance on how best to accomplish its goals. To be a more prudent purchaser under Medicare Part D, the Medicare Program must define what is covered and what should be covered with respect to professional services and clinical standards. The private sector has embraced home infusion drug therapy with more meaningful definitions and logical coverage policies. This enables private health plans to take advantage of the considerable cost savings achieved by administering these therapies in the home rather than the hospital setting.

¹ Durable Medical Equipment Regional Carriers (DMERCs).

Policymakers have not expanded Part B coverage of home infusion therapy because it was widely accepted that the best means of establishing proper coverage for home infusion therapy is through passage of a comprehensive Medicare outpatient prescription drug benefit, which would include broadened coverage of infusion drugs provided in the home. That has now happened. The Part D benefit is the opportunity to ensure that home infusion drug therapies are widely available to Medicare beneficiaries in the same manner they are available to private pay patients.

Overview of Infusion Drug Therapies Under Medicare Part B in the Home

The coverage of infusion drug therapies in the home setting is currently limited to the subset of infusion therapies that require use of an infusion pump. Reimbursement is limited to the equipment, drugs and supplies. In contrast, well-established standards of care in the private sector require that certain pharmacy and nursing services be provided with the administration of home infusion drug therapy. Medicare Part B, however, does not make separate payment for such services and there are no existing Medicare standards that require adherence to these or comparable standards of care.² The recent Medicare legislation requires CMS to develop quality standards for therapies covered under the DME benefit, and this provides an opportunity for CMS to develop meaningful standards that are unique to the infusion community.

The fact that Part B coverage in the home setting is limited generally to infusion drugs that require an external infusion pump^{3,4} means that a number of important infusion drug therapies that could be provided safely and cost-effectively in the home are not covered. Non-covered therapies include drug infusions that can be run into the body intravenously by gravity without the precision of regulating the flow with an infusion pump. For example, many intravenous antibiotics are not covered in the home for this reason, although private payers regularly cover such therapies (often saving the expense of providing coverage in a more expensive inpatient setting).

To provide infusion drug therapies in the home under the DME benefit, national Medicare policy requires that suppliers obtain state licensure to dispense drugs, which typically is regulated through the state boards of pharmacy. The entities that provide these therapies tend to specialize in this area. The services involved in providing infusion therapy, as well as the pharmacy licensure requirements, make suppliers of infusion drug therapies readily distinguishable from typical DME suppliers or typical pharmacies.

² The Medicare Program does require suppliers of durable medical equipment to meet certain general requirements, but these supplier standards do not pertain to specific clinical issues such as the provision of infusion therapies.

³ The list of infusion drugs covered in the home setting under the DME benefit is limited to the following drugs: amphotericin B; deferoxamine mesylate; hydromorphone; dobutamine hydrochloride; epoprostenol; foscarnet sodium; ganciclovir sodium; insulin; meperidin hydrochloride; milrinone lactate; morphine sulfate; fentanyl citrate; doxorubicin HCL; bleomycin sulfate; cladribine; cytarabine; fluorouracil; floxuridine; acyclovir; vinblastine sulfate; vincristine sulfate. Other drugs might be covered for home infusion drug therapy under the appropriate miscellaneous code on an individual consideration basis, if the regional carriers that handle DME claims (DMERCs) find that the drug requires an external infusion pump and the drug is medically necessary.

⁴ Although the primary mechanism for coverage of infusion drug therapies in the home is the DME benefit, for the sake of completeness, please note that several infusion drug therapies are covered in the home setting under the applicable regional medical policies for immunosuppressive drugs. The list of infusion drugs covered in the home setting under the DMERC medical policy for immunosuppressive drugs is limited to the following drugs: azathioprine and methylprednisone sodium succinate.

Professional Services and Standards of Care in the Home Setting

Perhaps as important as stating what is covered expressly under the DME benefit, it is important to highlight that there is no separate payment under Medicare Part B for the professional pharmacy and nursing services required to meet the standards of care that are common in the private sector. Payment for such functions and costs are subsidized through reimbursement for the drugs, equipment, and supplies. Most observers, including the General Accounting Office, criticize this approach.

Additionally, Medicare Part B does not enforce or require adherence to any clinical standards for the provision of home infusion drug therapy, although private sector payers often require credentialing or adherence to the standards promulgated by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) or a similar national credentialing organization.

The Role of Home Health Agencies

It is also worth noting that most home health agencies (HHAs) do not have state pharmacy licenses and do not provide home infusion drug therapies as part of their range of services. In the event that beneficiaries who qualify for care under the HHA benefit (for example, they meet the Program's definition of "homebound") also require home infusion drugs, the infusion drug therapy usually is provided by a supplier specializing in this area that maintains proper state pharmacy licensure. The infusion therapy would be covered by Medicare separate and apart from the services covered under the HHA benefit. There are, of course, HHAs that have established pharmacies and can offer infusion therapy drugs and services.

It also is important to note that private health plans designate the home infusion pharmacy as the primary provider for patients requiring infusion drug therapy – not home health agencies – because the home infusion provider is expert in the clinical management and care coordination of these patients. Home infusion pharmacies are required to meet distinct standards that are vital to safe and effective infusion care.

Conclusion

The benefit methodology in Medicare Part B coverage for infusion drug therapies is not suitable for implementation of the new infusion drug coverage under Part D. The DME benefit is designed to compensate DME suppliers for the provision of medical equipment. In contrast, home infusion providers also must provide professional pharmacy and other clinical services to achieve good patient outcomes. For that reason, the vast majority of private sector payers require accreditation for home infusion providers.

The lack of any separate payments for administration of infusion drug therapy in the home setting to cover the professional pharmacy or nursing services makes homecare providers especially vulnerable to pricing changes for those components of the therapy that are covered (for example, the drugs). This aspect of home infusion therapy is distinguishable from infusion therapy provided in physician office settings where separate codes and fees do exist for the administration of infusion drug therapy. We believe that, in recognition of this vulnerability for home infusion drug therapy under Medicare Part B, Congress left reimbursement for the drug component of home infusion drug therapy untouched in the near future.

Thus, we believe it is important to recognize that the existing limited coverage model for some infusion drug therapies under Medicare Part B is an antiquated model that is inconsistent with the approach used by private payers. To ensure meaningful access for beneficiaries to home infusion drug therapy, the Medicare program should look to the well-established private sector coverage in its roll out of Part D coverage for home infusion drug therapy.

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