Medicare Reform Needed for Home-Based Low-Molecular-Weight Heparin Therapy

To the Editor: Similar to its policy regarding parenteral antibiotics, Medicare currently reimburses for the administration of low-molecular-weight heparin (LMWH) in office, clinic, and emergency department settings but does not pay for home-based treatment. Individual Medicare patients must provide out-of-pocket payment for home-based LMWH treatment or choose to remain in the hospital or go to a nursing home to complete intravenous heparin therapy. Paradoxically, if Medicare patients who are homebound and receiving home health care nursing receive outpatient (office- or clinic-based) LMWH therapy, they become ineligible for home nursing benefits.

More than a dozen randomized clinical trials have compared outpatient (including at-home) LMWH therapy to unfractionated heparin for initial management of venous thromboembolism and found LMWH to be safe and at least as effective as unfractionated heparin in reducing the incidence of recurrent, symptomatic deep venous thrombosis, pulmonary embolism, and death.[1,2] The potential magnitude of cost savings with use of outpatient-based LMWH therapy is substantial. Segal et al[2] systematically reviewed 19 studies involving outpatient LMWH therapy that addressed the issue of costs via direct comparison or decision analysis and reported a median cost savings of 57% with LMWH vs unfractionated heparin use. In a cost-minimization analysis, van Den Belt et al[3] determined that substitution of in-hospital heparinization with at-home LMWH therapy would result in a 64% reduction in costs. According to decision-analysis modeling, treatment with LMWH resulted in cost savings when as few as 8% of patients were treated at home.[4] Two studies, 1 from Canada[5] and 1 from the United States,[6] comparing outpatient enoxaparin with in-hospital unfractionated heparin for treatment of deep venous thrombosis reported cost savings per treatment course of $2422 (57%) and $3025 (60%), respectively. The average cost reduction in these 2 studies was $2724, and with an overall mean age- and sex-adjusted annual incidence of deep venous thrombosis in the United States of 48 per 100,000 population (160,640 new cases per year),[7] the national financial impact of a strategy using outpatient LMWH therapy can be as much as $435 million annually.

In the mid-1980s, reimbursement for home intravenous antibiotic therapy by third-party payers paradoxically lagged behind accumulated literature evidence that confirmed its safety, efficacy, and cost-saving benefits.[8] Within the private insurance industry, logic eventually caught up with logistics, and home parenteral antibiotic treatment became the cornerstone of management for a variety of infectious disease syndromes that has reduced treatment costs while ensuring clinical outcomes that equal those provided by in-hospital antimicrobial therapy. Today, Medicare still does not reimburse for home intravenous antibiotics, or LMWH, but does provide coverage for home-based care, with strict guidelines, for the following parenteral medications: antirejection agents (eg, cyclosporine, tacrolimus), cancer chemotherapeutic agents (eg, cyclophosphamide, etoposide), narcotic analgesics (eg, morphine sulfate, fentanyl), deferoxamine, insulin, inotropic agents (eg, dopamine, dobutamine), agents for pulmonary hypertension (eg, epoprostenol, treprostinil), antiviral agents (eg, acyclovir, ganciclovir), and antifungal agents (eg, amphotericin B deoxycholate, amphotericin B liposomal complex). Medicare reform is needed to address the inconsistency of home treatment reimbursements.

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Celiac Disease Serology and Irritable Bowel Syndrome: Does the Relationship Merit Further Evaluation?

To the Editor: We read with interest the study by Locke et al[1] in the April 2004 issue of *Mayo Clinic Proceedings* on the prevalence of celiac disease serology in individuals with well-categorized irritable bowel syndrome (IBS) and dyspepsia in a primary care setting. The authors observed that the prevalence of tissue transglutaminase (TTg) was 4% (2/50), but because these individuals were endomysial antibody–negative, they did not undergo duodenal biopsy. The authors concluded that celiac disease does not explain the IBS symptoms in the vast majority of patients in a US primary care population. We were surprised by this conclusion for several reasons.

Endomysial antibody–negative celiac disease in the presence of TTg positivity has been well described.[2] Therefore, the 2 patients with IBS and positive TTg tests could have had celiac disease—we will never know without duodenal biopsy.