

# 21<sup>st</sup> Century Cures Act: Unintended Impact on Home Infusion Patients

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## Introduction

The 21<sup>st</sup> Century Cures Act made two significant changes to Medicare reimbursement for home infusion therapies, which are relied on by Medicare beneficiaries to treat illnesses ranging from cardiac disease to immunodeficiency to others. The two changes were:

- After consensus among patient groups and stakeholders, *The Act* created a new reimbursement model for home infusion that remedied Medicare's inadequate reimbursement for home infusion therapies in the past. This provision, Section 5012 of The Act, was well received by patients and advocates and is scheduled to be implemented by the Centers for Medicare & Medicaid Services (CMS) in 2021.
- *The Act* also included a provision, Section 5004, which dramatically cut reimbursement for home infusion therapy beginning in January of this year. Specifically, associated service costs that were previously adequately covered by the drug reimbursement are no longer covered. This has created a "care gap" between 2017 and 2021 where patient access to these therapies is threatened. Further, it is likely that, in the absence of in-home availability, patients will migrate to the hospital setting for these therapies, increasing costs to the Medicare program.<sup>1</sup>

We are asking Members of Congress to act to remedy this care gap and ensure that patients can continue to receive lifesaving home infusion therapies and services by providing adequate reimbursement for home infusion during this interim period.

## Background

The comprehensive cognitive services necessary to manage Medicare beneficiaries requiring home inotropic therapy and subcutaneous immunoglobulin (SCIg) therapy are complex. These services include pharmacist sterile IV compounding and dispensing, clinically monitoring of patient's laboratory results and response to therapy, nurse monitoring of vital signs and weights for patients, pharmacist and nurse on-call availability to patients 24/7, and nurses teaching patients to administer their therapy.<sup>2</sup>

### Home Inotropic Therapy

Home inotropic therapy is a life-sustaining continuous intravenous drug therapy prescribed to treat patients with severe congestive heart failure. The therapy alleviates symptoms, keeps

patients alive and in the comfort of their home, and is prescribed purely for symptom palliation or as a bridge to ventricular assist device implant or heart transplant.

This is a very complex therapy that involves significant clinical and patient management oversight by physicians, pharmacists, and nurses. Over the last 20 years, this therapy has proven to be a safe and effective home therapy when the homecare is managed by a clinically competent home infusion pharmacy. Home inotropic therapy has demonstrated positive outcomes including a decrease in hospital readmissions and unnecessary emergency department visits, coupled with high patient satisfaction.<sup>3</sup>

The prevalence of heart failure (HF) and associated medical costs are significant, particularly among Medicare beneficiaries. According to a 2015 Milliman report, "the American Heart Association estimates that 5.7 million Americans are currently living with HF...HF incidence approaches 10 per 1000 population after age 65 and prevalence increases with age."<sup>4, 5</sup> The report goes on to say, "By examining current HF prevalence along with US Census estimates of population growth, researchers predict that HF prevalence will increase approximately 46% in the next 15 years, resulting in over 8 million American adults with HF by 2030."<sup>4, 6</sup>

Highlighting the financial impact of heart failure on the healthcare system, "in 2012, the total direct medical cost for HF was \$20.9 billion, and this is expected to increase to \$53.1 billion in 2030 (representing a 2.5 fold increase). The majority of these costs are related to hospitalization."<sup>4, 6</sup> "HF is the most common discharge diagnosis among patients older than 65 years and the primary cause of readmission within 60 days."<sup>4</sup> With the implementation of the *21st Century Cures Act* reimbursement model and subsequent lack of access to home infusion, the result will be a direct increase in unnecessary hospitalizations, making the projected medical costs higher, at least until 2021 when associated clinical cost may be reimbursed for home services.

In 2010, the average length of stay per heart failure admission was 5.6 days<sup>7</sup> and in 2012, the average Medicare allowed cost per all-cause readmission following a HF admission was \$15,667,<sup>4</sup> equating to an average cost per day of \$2,798. Under the recently discontinued Medicare reimbursement model for home inotropic infusion, the average cost per day was approximately \$350, which was inclusive of the cost of the drug and associated services required to care for these patients.<sup>8</sup>

In addition to the financial impact on Medicare beneficiaries, there are also clinical and quality of life implications. Beneficiaries will be forced to remain in an acute care setting which will place them at risk for more complicated and costly health problems such as hospital-acquired infections and incident delirium.<sup>9</sup> Many older adults also suffer from activity limitations and/or have limited access to transportation and, therefore, may be burdened by increased frequency of physician appointments.<sup>10</sup>

Beneficiaries may opt to discontinue treatment rather than remaining as an inpatient, which will trigger an exacerbation of symptoms, resulting in decreased quality of life and increased

unplanned physician appointments, emergency department visits and hospitalizations. Beneficiaries will also lose the choice of treatment simply for symptom palliation, improved quality of life, and the opportunity to die at home (which most patients prefer).<sup>11</sup>

### Subcutaneous Immunoglobulin Therapy (SCIg)

Home subcutaneous immunoglobulin therapy (SCIg) is a drug therapy prescribed to treat patients with primary immunodeficiency, allowing patients to optimize their health and improve their quality of life. SCIg therapy replaces antibodies that are deficient in the blood of these patients. Without this replacement therapy, immune-compromised individuals are susceptible to life-threatening infections that require hospitalizations and further therapeutic interventions.

SCIg therapy provides patients the independence at home to self-administer their medication without the costly expenses associated with an outpatient infusion center or similar site of care, where a licensed nurse will be required to administer the infusion. Taking away the option of therapy in the home, which the majority of patients prefer, significantly affects their freedom in dealing with an already challenging disease state.<sup>12, 13, 14, 15</sup>

If forced to receive therapy outside the home, patients will be placed at risk for more complicated and costly health problems, such as hospital-acquired infections. Exposure to infection in an infusion center where there are numerous patients simultaneously receiving infusion therapy is of particular concern for immunosuppressed patients.<sup>9</sup> In addition, many older adults suffer from activity limitations and/or have limited access to transportation and, therefore, may be burdened by traveling outside the home for treatment.<sup>10</sup>

The financial impact can be significant between home administration and the hospital outpatient setting for intravenous immunoglobulin. The administration of home immunoglobulin (Ig) is more cost-effective than any other site of care.<sup>16</sup> Prior to the *21st Century Cures Act* payment reduction, the mean cost per patient infusion for Ig on average was \$4,745 in the hospital outpatient setting versus \$3,293 in the home or 31% less than the higher cost setting.<sup>16</sup>

### **Conclusion**

Since the 1980's, commercial payers have recognized home infusion providers' associated clinical services component and reimburse a daily fee for them, called a per diem.<sup>17</sup> The *21st Century Cures Act* does not include reimbursement for associated service costs that were previously adequately covered by higher drug reimbursement until 2021 and as a result, the majority of Medicare beneficiaries receiving home inotropic and SCIg therapy will move to the higher cost acute care or hospital outpatient infusion center.

Given the reduction to the drug reimbursement, it is imperative that the payment, or per diem, for associated home infusion clinical services be implemented as soon as possible, and effective January 1, 2018. The current four-year gap must be eliminated to ensure beneficiaries have

continued access to this care. Congress should reset the effective date of the Section 5012 payment for home infusion services to 2018, and provide CMS a “transition rate” (using the upper payment limit already in Section 5012 of the 21<sup>st</sup> Century Cures Act) to allow for treatment of these patients as soon as possible.

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