Impact on Medicare Expenditures From Expanding Coverage of Infusion Therapy of Anti-Infective Drugs to the Home Setting

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Avalere
National Home Infusion Association
EXECUTIVE SUMMARY

Infusion therapy involves the administration of medication through a needle or catheter. It is prescribed when a patient’s condition cannot be treated effectively by oral medications. At one time, patients receiving infusion therapy had to remain in the inpatient setting for the duration of their therapy. As a result of heightened emphasis on cost-containment in healthcare, as well as developments in the clinical administration of the therapy, today many patients in need of infusion therapy receive services in a variety of skilled nursing, ambulatory, and home settings. Patients who receive infusion therapy in a Hospital Outpatient Department (HOPD) or physician’s office are generally receiving short-term therapy. Currently Medicare covers infusion therapy in the hospital, skilled nursing facility (SNF), physician office, and HOPD.

According to a June 2010 Government Accountability Office report,¹ most, if not all, commercial health plans cover home infusion therapy services, and many of these insurers also provide comprehensive coverage under their network-based Medicare Advantage plans. In contrast, Medicare’s fee-for-service (FFS) program (Parts A and B) does not cover the full range of services for the provision of infusion therapies in a patient’s home. Medicare Part B does cover a limited number of drugs infused using an infusion pump but does not separately cover the clinical services necessary for the provision of infusion therapy in the home. In addition, while most infusion drugs that are not covered by Part B may be covered under the Medicare Part D prescription drug benefit; infusion-related services are not covered. Home healthcare services, including skilled nursing services, are only covered when a beneficiary meets the criteria for homebound status as defined under Medicare’s home health benefit.

The National Home Infusion Association (NHIA) has proposed expanding coverage under Medicare’s FFS program for home infusion therapy. For drug administration services (professional services, equipment and supplies) for anti-infective drugs there would be a $120 Part B per diem payment for each calendar day between initiation and termination of home infusion services. The level of intensity of drug administration services can vary across different types of home infusion services and it is envisioned that this amount would be higher or lower, depending on the type of therapy involved. Drugs infused at home would be covered under Part D, regardless of whether these drugs were previously covered by Part B, by Part A (under the SNF benefit), or through some other coverage. Part D Prescription Drug Plans (PDPs) currently pay for these drugs (when currently covered by Part D), and we assume payments for these drugs would continue to be based on rates negotiated with PDPs. Additionally, this proposal is intended to cover “intensive” home infusion needs, defined as needing infusion therapy for three or more days.
NHIA asked Avalere Health to assess the potential Medicare savings (reduced Medicare program expenditures) of expanding Medicare coverage of infusion therapy in the home. We approached the analysis in two stages. First, we identified a clinically coherent set of conditions characterized by short-term, intensive therapy most prevalent among home infusion recipients. To identify this focused set of patients, we used a sample of NHIA member company data representing services provided to the population age 65 or older in calendar year 2011 by a variety of providers, including privately held, publicly traded, and hospital-owned or affiliated providers representing single site, multi-site, regional, as well as national providers. The analysis showed that anti-infective therapy constitute the largest portion of the infusion drug therapies that home infusion companies provide to their patients age 65 years and older, and the infusion regimens tend to require multiple infusions per day for a relatively defined period of time.

The second stage used Medicare claims data to estimate the potential savings to Medicare that could arise from patients migrating from skilled nursing and ambulatory settings to home infusion. Of patients with a primary infection diagnosis and receiving infusion of anti-infective drugs, we assume a random 10 percent receiving infusion in physician offices, a random 50 percent from HOPDs and a random 23 percent from SNFs (varying by the functional limitations and intensity of services provided) would begin receiving infusion services in the home setting. We were unable to segment patients receiving infusion in physician offices and HOPDs by acuity. However, we assume that only the setting for infusion services changes and that they would continue to receive all other services in their current settings.

The analysis allowed for a “crowding out effect” associated with beneficiaries that either currently pay out of pocket or are covered by a third-party insurer for infusion services that Medicare does not currently cover, but would be a new cost to the program. However, given that the decision rests with physicians to prescribe the drug and not home infusion providers, we did not anticipate an increase in infused antibiotics over oral antibiotics, or “woodwork effect.”

This analysis does not attempt to calculate (or address) the savings associated with beneficiaries avoiding hospital stays. Since a three-day hospital stay is necessary for Medicare coverage of a SNF stay, avoiding hospitalizations may also lead to avoiding additional SNF stays. Furthermore, while a recent CDC study states the annual cost to hospitals of healthcare-associated infections (HAIs) in the US exceeds $40 billion dollars, our analysis does not attempt to address the potential additional savings from payment reductions resulting from system-wide lower costs associated with the decreased risk of HAIs from patients migrating from institutional settings to home.
RESULTS: MEDICARE COVERAGE OF HOME INFUSION FOR ANTI-INFECTIVE THERAPIES WILL LIKELY YIELD SAVINGS OVER 10 YEARS OF MORE THAN 12 PERCENT ($80 MILLION)

Overall, the results of the analysis indicate that savings are likely using a per diem payment of $120 dollars for anti-infective therapy. For anti-infective therapy, we estimate that there would be a savings of 12.6 percent of the overall cost of infusion services that migrate from HOPDs, physician offices, and SNFs to home for the 10-year period from 2015 to 2024, or $80 million. The one-year savings in 2014, on which future savings are based, would be $8.5 million (17.7 percent). This savings percentage exceeds the 10-year savings percentage because drug prices, which we assume home infusion providers cannot control, are expected to rise faster than provider payments for administration services. The number of SNF patients receiving infused drugs is likely underestimated because coding for these services on the claim is not mandatory, so savings may in fact be higher. Furthermore, even if the volume of all Medicare-covered anti-infective infusion services (in all settings, not just in the home) rose by 7.4 percent as a result of the new coverage—from patients paying out of pocket for the home administration services—these payment parameters for anti-infective therapy would be budget-neutral.
BACKGROUND

Landscape of Infusion Therapy

Infusion therapy involves the administration of medication through a needle or catheter. It is prescribed when a patient’s condition cannot be treated effectively by oral medications. At one time, patients receiving infusion therapy had to remain in the inpatient setting for the duration of their therapy. Heightened emphasis on cost-containment in healthcare, as well as developments in the clinical administration of the therapy, led to strategies to administer infusion therapy in alternate settings.

Today, many patients in need of infusion therapy receive services in a variety of settings, including: HOPDs, physician offices, skilled SNFs, and in the home. Patients who receive infusion therapy in a HOPD or physician’s office are generally receiving short-term therapy. For example, Avalere’s analysis of HOPD and physician office claims reveal that antibiotic drug utilization for anti-infective therapy reflect those Healthcare Common Procedure Coding System (HCPCS) codes that are typically dosed once per day (e.g., azithromycin, ceftriaxone sodium, daptomycin, ertapenem sodium, garamycin/gentamicin, vancomycin, levofloxacin, telavancin).

To describe the types of patients currently receiving home infusion therapy, we collected a sample of NHIA member company data representing services provided to the population age 65 or older in calendar year 2011. Data contributors included privately held, publicly traded, and hospital-owned or affiliated providers representing single site, multi-site, regional, as well as national providers. We used these data along with the Agency for Healthcare Research and Quality’s (AHRQ) Clinical Classification Software (CCS) tool to cluster patient diagnosis and procedures into clinically meaningful categories to illuminate the types of patients currently treated in the home.

The analysis shows that diseases and medical conditions commonly treated in the home with infusion therapy for the 65 and older population include: skin and skin structure infections (SSSI); pain management; infectious arthritis; cancer (predominantly bladder and colon cancer); septicemia; pneumonia; gastrointestinal disorders including Crohn’s disease; and complications resulting from medical procedures.

As shown in Figure 1, the 10 most frequent diagnoses (grouped by CCS category) account for approximately one-half of all home infusion claims in the NHIA member company data. Furthermore, infections account for about one-half of these top 10 conditions.
Expanding Coverage of Infusion Therapy

Many antibiotics infused in the home require intermittent dosing multiple times per day—from two to six doses, depending on the drug(s) to which the infectious organism is susceptible, as well as the patient’s diagnosis and ability to metabolize and clear the drug. According to this analysis of home infusion company claims, these intermittently dosed antibiotics are currently being delivered in the home environment to patients with commercial insurance, including the 65 and older Medicare Advantage (Part C) patients.

According to NHIA, infusion in the home is commonly covered by Medicare Advantage plans. However, due to the lack of Medicare coverage of infusion in the home under the fee-for-service (FFS) program, NHIA asserts, based on discussions with hospital discharge planners, that many beneficiaries who require intermittent antibiotic infusions are admitted to SNFs to receive their infusion of these drugs when their clinical condition otherwise does not warrant institutional care. According to these discussions, post-acute care decisions are often made by considering multiple factors including a beneficiary’s clinical needs, insurance coverage for needed services, as well as family support for care at home and also the ability of the patient to make the frequent trips to an ambulatory setting for the duration of treatment required.

Figure 1. Six of the Top 10 Most Frequent Diagnoses among Patients Receiving Home Infusion Are Anti-Infective Related

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>Percent of Home Infusion Claims</th>
</tr>
</thead>
<tbody>
<tr>
<td>Skin &amp; Skin Structure Infection</td>
<td>9.2%</td>
</tr>
<tr>
<td>Other Diagnoses of Bladder</td>
<td>6.4%</td>
</tr>
<tr>
<td>Infectious Arthritis</td>
<td>6.3%</td>
</tr>
<tr>
<td>Colon Cancer</td>
<td>6.3%</td>
</tr>
<tr>
<td>Septicemia</td>
<td>5.9%</td>
</tr>
<tr>
<td>Pneumonia</td>
<td>4.0%</td>
</tr>
<tr>
<td>Complications of Procedures</td>
<td>3.4%</td>
</tr>
<tr>
<td>CHF</td>
<td>3.1%</td>
</tr>
<tr>
<td>Other Bacterial Infections</td>
<td>3.0%</td>
</tr>
<tr>
<td>Fluid/Electrolyte Diagnoses</td>
<td>3.0%</td>
</tr>
</tbody>
</table>

Note: Diagnoses grouped by AHRQ Clinical Condition Software (CCS) category
Source: Sample of NHIA member company data
**Current Coverage of Home Infusion**

According to a June 2010 Government Accountability Office report, most, if not all, commercial health plans cover home infusion therapy services. The study also points out that many insurers also provide comprehensive coverage under their network-based Medicare Advantage plans, which may provide benefits beyond those required under Medicare FFS. The study found that services are typically paid for with a per diem amount that includes clinical services, supplies, and equipment and a separate fee schedule payment for drugs and nursing visits. Beyond commercial insurers, NHIA asserts that many state Medicaid programs, Tricare, and the Veterans Administration provide coverage for home infusion.

Currently Medicare’s FFS program (Parts A and B) covers infusion therapy in the hospital, SNF, physician office, and HOPD, but does not cover the full range of services for the provision of infusion therapies in a patient’s home. Medicare Part B covers a limited number of infused drugs in the home under the Durable Medical Equipment (DME) benefit when the patient meets the medical necessity criteria detailed in the Local Coverage Determination (LCD) and the drug is infused using an infusion pump. For these Part B covered infused drugs, Medicare pays for the drug, the infusion pump and related supplies per a fee schedule. Medicare Part B does not separately cover the clinical services necessary for the provision of infusion therapy in the home.

While most infusion drugs that are not covered by Part B under the DME benefit for use at home may be covered under the Medicare Part D prescription drug benefit, infusion-related services—such as clinical management of the patient, care-coordination, equipment and supplies—are not covered. Home health care services, including skilled nursing services, are only covered when a beneficiary meets the criteria for homebound status as defined under Medicare’s home health benefit. There may be patients who could benefit from home infusion, but do not necessarily meet the definition of homebound, and thus do not qualify for home health coverage.
Provision of Home Infusion Services

Infusion therapy originates with a prescription order from a qualified prescriber who is overseeing the care of the patient. An infusion therapy provider is a state-licensed pharmacy that specializes in provision of infusion therapies. There are specialized services, supplies, and equipment that are necessary to ensure quality practices and outcomes for home infusion services. An infusion pharmacy ensures infusion drugs are:

- Compounded in a sterile environment
- Maintained in appropriate conditions to ensure sterility and stability
- Administered at the right dose and on the right schedule
- Administered using the appropriate vascular access device (often a long-term device), which is placed in the correct anatomical location based on the expected duration of therapy, the pH, osmolarity, and osmolality of the medication, and maintained using the proper flushing solution between doses
- Administered using an appropriate drug delivery device
- Monitored for adverse reactions and therapeutic efficacy

According to NHIA, infusion pharmacy staff, infusion nurses, and dietitians are key members of the patient’s infusion care team. These clinical professionals work closely to coordinate each patient’s care plan with the physician and other members of the patient’s health care team. When infusion therapy is provided in a patient’s home, NHIA asserts that the infusion nurse will ensure proper patient education and training, and, in concert with the infusion pharmacist, will monitor the care of the patient in the home. They typically provide such services (as required for accreditation) as:

- Evaluation
- Assessment
- Education and training for the patient or caregiver
- Inspection and consultation of the home environment
- Access device care and maintenance

Using the education and training provided, caregivers and/or patients are successfully able to administer their infusion therapies on their own. After initial consultation, the infusion nurse will return once or twice a week to the home to ensure that the patient’s vascular access device is maintained properly and to ensure proper patient self-administration. The clinical care team is on-call 24/7 to address any patient questions that may arise.

Organizations that accredit home infusion providers include the Accreditation Commission for Health Care, the Community Health Accreditation Program, and the Joint Commission. These organizations accredit home infusion providers with care standards related to patient and home environment assessment, patient and caregiver education, ongoing monitoring of clinical status, and medication preparation, delivery and administration.
PROPOSAL

NHIA proposes coverage for home infusion therapy with two types of payments—one for drug administration services (professional services, equipment and supplies) and a separate payment for the infused drug(s). NHIA proposes a Part B per diem payment for each calendar day between initiation and termination of home infusion services. The level of intensity of drug administration services can vary across different types of home infusion services and it is envisioned that this amount would be higher or lower, depending on the type of therapy involved. Drugs infused at home would be covered under Part D, regardless of whether these drugs were previously covered by Part B, by Part A (under the SNF benefit), or through some other coverage. Part D Prescription Drug Plans (PDPs) currently pay for these drugs (when currently covered by Part D), and we assume payments for these drugs would continue to be based on rates negotiated with PDPs. Additionally, this proposal is intended to cover “intensive” home infusion needs, which is defined as a patient who needs infusion therapy for more than three days.
METHODS AND ASSUMPTIONS IN THE AVALERE ANALYSIS

Infusion services involve a wide variety of therapies and indications with different mixes of settings where the infusions are administered. Therefore, we focused our analysis on anti-infective therapies. As demonstrated the NHIA member-supplied data, anti-infective therapy constitute the largest portion of the infusion drug therapies that home infusion companies provide to their patients age 65 years and older, and the infusion regimens tend to require multiple infusions per day for a relatively defined period of time.

Our approach to the analysis was to combine Medicare claims data with migration assumptions of what percent of patients would move from various settings of care to receiving treatment in the home. In lieu of information about how many patients may receive home infusion services and pay out of pocket for the administration, we estimated the percent of FFS beneficiaries that could result in a “crowding out effect” and still allow for the proposal to be budget-neutral. Such an effect would account for costs associated with beneficiaries that either currently pay out of pocket or are covered by a third-party insurer for infusion services that Medicare does not currently cover. If coverage were expanded, some costs might be shifted from the beneficiary or another insurer to the Medicare program. Given that the decision rests with physicians to prescribe the drug and not home infusion providers, we did not anticipate an increase in infused antibiotics over oral antibiotics or “woodwork effect.”

Our analysis did not attempt to address any potential savings (reduced Medicare program expenditures) associated with the decreased risk of healthcare-associated infections related to patients migrating from institutional settings to home. This analysis also does not address potential savings that would be associated with hospital avoidance.

We used the five percent Medicare Standard Analytic Files for 2011, specifically the physician/supplier, institutional outpatient, and skilled nursing facility claims files. Infusion of anti-infective therapies in physician offices and HOPD (or other clinics paid as such) were identified as claims with anti-infective drug HCPCS codes (“J-codes”) billed.

Infusion of anti-infective therapies in SNFs cannot directly be identified due to the lack of HCPCS reporting in inpatient (acute and SNF) settings. As a proxy, we identified likely anti-infective infusion cases as those with any diagnosis of acute infection (as defined using AHRQ Clinical Condition Software [CCS] categories 1 through 10) and also one or more billed revenue center codes of intravenous therapy (026x). The number of SNF patients receiving infused drugs is likely underestimated because coding for these services on the claim is not mandatory. Unfortunately, we do not have any information
on the degree to which we are underestimating SNF infusion frequency, so we made no further adjustment. We excluded those cases where complications and comorbidities would likely necessitate the patient’s stay in a SNF.

We assumed a certain percentage of patients would migrate from these three settings and receive services in the home with this new coverage. We assumed 50 percent of patients will migrate from HOPDs to the home setting. Underlying this assumption is the belief that physicians who are given the opportunity to safely offer a patient care in the home will do so for their patients if the patient would otherwise receive the drug in the HOPD setting.

However, we assumed that a significantly smaller percent of infusion services provided in physician offices would migrate to home infusion, only 10 percent. Physicians currently set up to provide infusion services in their office may tend to have sophisticated operations for infusing relatively significant numbers of patients. In addition, physicians who frequently infuse these drugs in their offices may be able to obtain these drugs for favorable prices relative to reimbursement, which helps the sustainability of their practice and would provide no financial incentive to encourage home infusion. Furthermore, and perhaps at least equally important, physicians who set up infusion suites in their offices may feel that is the most appropriate infusion setting. That said, we do recognize that strong patient preferences, availability of necessary caregiver support, and any other reason for physician openness to home infusion, may overcome financial or any other incentives for physicians to infuse drugs in their offices.

With respect to patients who currently receive infusion therapy in both the hospital outpatient and physician office setting, we assumed 20 percent of patients would migrate to the home setting. When patients received care in both settings, drug utilization in the physician office setting reflected about 69 percent of total drug units, whereas drug utilization in the HOPD setting reflected 31 percent. Twenty percent seemed like a practical assumption given that the combined services tend to be done more in the physician office setting.

Our assumptions for how patients would migrate from SNFs are based on a more detailed analysis of the SNF patients who are likely receiving infused anti-infective therapies. For each Resource Utilization Group (RUG), we used a combination of the RUG definition—including the amount of therapy received per week, nursing and special services provided, and activity of daily living (ADL) limitations—and clinical judgment of home infusion providers for the likelihood of appropriateness for home infusion to inform the assumption of the migration assumption. Generally speaking, we assumed that patients with many ADL deficits would be less likely (if at all) appropriate for home infusion. This is true for patients at varying levels of service intensity/complexity, though
as service intensity/complexity rises, the percentage of patients appropriate for home infusion would fall. Furthermore, the intensity of therapy services provided influenced migration assumptions. We assumed that patients receiving low levels of therapy are likely unable to participate in therapy because of low levels of physical or cognitive function and may not be physically capable to infuse drugs in the home. We also assumed that patients with particularly high therapy intensity may need an inpatient level of care to receive that level of therapy along with frequent infusions. We have included these assumptions in the appendix document for this report. Finally, we assumed that only the portion of a SNF stay in which infusion is provided would migrate to home infusion; if infusion was only provided for half of the stay, only half of the stay would migrate. We implemented this assumption by assuming SNF claims (which often have a duration of one month or less) would migrate, not entire SNF stays. Under these assumptions, approximately 23 percent of SNF patients receiving infused drugs in the facility, about 0.2 percent of all SNF patients, would instead receive infusions at home.

Under current law, Medicare program payments for infused drugs vary by setting. For physicians, payment is made on a fee-for-service basis (limited to 106 percent of average sales price). For hospital outpatient departments, payment may be packaged into the payment for the visit or may be made separately, depending on the cost of the drug. For SNFs, the payment for the drug is completely bundled into the RUG payment. Under Part D, the actuarial cost of the plan’s payment for the drug is built into the bid price. For estimating the change in Medicare program expenditures under this proposal, we first identified the actual Medicare program payments for drugs in claims (based on setting, in many cases was $0), updated to 2014. We compared this to a volume-weight average of Part D plan mail-order prices, multiplied by 67 percent to reflect plan payments for these drugs that would be incorporated into plan bid in future years.

We assume that patients currently receiving physical therapy, occupational therapy, and speech/language pathology services during their SNF stay will receive such services in ambulatory (in private practices or hospital or freestanding clinics) settings. To estimate the amount of therapy they would receive, we used the therapy use classification encoded in the RUG category in combination with estimates of therapy time from CMS’ Staff Time and Resource Intensity Verification (STRIVE) study. This study estimated actual average therapy time, adjusted for individual versus group therapy, for patients in SNFs and relative therapy time for the different therapy use levels (low, medium, high, very high, and ultra-high).

We were unable to segment patients receiving infusion services by the severity of their case. As a result, within the set of patients who met the criteria to potentially receive infusion of anti-infective drugs in the home, we randomly assigned patients to shift from
office, HOPD, or SNF to home. We acknowledge that almost surely there is a relationship between patient acuity and the safety/clinical appropriateness of infusion in the home. However, we are only assuming that the setting for infusions may shift to the home and that the patient will continue to receive other services in their current settings. The impact of systematic differences in patient acuity on the cost of the infusion services is therefore unclear.

We then estimated the 10-year savings from expanding coverage of infusion therapy to home. Using the 2011 Medicare claims data and the methods described above, we estimated a one-year savings for 2014, incorporating actual payment growth rates from 2011 to 2014. To estimate savings over the 10 years from 2015 to 2024, the earliest feasible implementation period, we used the Congressional Budget Office (CBO) April 2014 Medicare Baseline\(^5\) plus Medicare FFS enrollment growth estimates from the 2013 Medicare Trustees’ Report\(^6\) to estimate annual growth rates under current and proposed laws. We incorporated the growth in payment rates (including assuming that the home infusion per diem payment would increase annually with the Consumer Price Index of Urban Consumers [CPI-U] minus the multifactor productivity adjustment) as well as growth in Medicare FFS enrollment, but did not incorporate any estimate of increases in utilization intensity.
RESULTS

Overall, the results of the analysis indicate that savings (reduced Medicare program expenditures) are likely using a per diem payment of $120 dollars for anti-infective therapy. For infusion of these drugs in the home, we estimate that there would be a savings of 12.6 percent of the overall cost of infusion services that migrate from HOPDs, physician offices, and SNFs to home for the 10-year period from 2015 to 2024, or $80 million. The one-year savings for 2014 would be $8.5 million (17.7 percent). This one-year savings percentage exceeds the 10-year savings percentage because drug prices, which we assume home infusion providers cannot control, are expected to rise faster than provider payments for administration services.

Based on the migration factors described above, Avalere estimates that about 23 percent of patients receiving anti-infective infusions in a facility (approximately 0.2 percent of all SNF patients) would begin receiving infusion services in the home setting (the number of SNF patients receiving infused drugs is likely underestimated because coding for these services on the claim is not mandatory). Furthermore, even if the volume of all Medicare-covered anti-infective infusion services (in all settings, not just in the home) rose by 7.4 percent as a result of the new coverage—from patients paying out of pocket for the home administration services—these payment parameters for anti-infective therapy would be budget-neutral.

Table 1. Base Year (2014) and 10-Year (2015-2024) Medicare Program Expenditures on Infusion Services Estimated to Migrate to the Home Setting, Under Current and Proposed Law, by Current Setting ($ Thousands)

<table>
<thead>
<tr>
<th>Current Setting</th>
<th>Current Law (Current Settings)</th>
<th>Proposed Law (Home Setting)</th>
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</thead>
<tbody>
<tr>
<td>HOPD</td>
<td>$19,267</td>
<td>$264,473</td>
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<tr>
<td>Physician Office</td>
<td>$2,884</td>
<td>$40,515</td>
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<tr>
<td>HOPD &amp; Physician Office</td>
<td>$1,050</td>
<td>$14,531</td>
</tr>
<tr>
<td>SNFs</td>
<td>$24,675</td>
<td>$312,686</td>
</tr>
<tr>
<td>Total</td>
<td>$47,876</td>
<td>$632,204</td>
</tr>
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Notes: Amounts in thousands of dollars. Current law indicates spending for infusion in the setting where the patient is currently receiving infusion; proposed law indicates spending for infusion in the home setting. Ten-year estimates incorporate CBO estimates of increases in payment rate factors plus Medicare Trustees’ estimates of Medicare Fee-for-Service (FFS) enrollment from 2015 to 2024. Sources: Avalere Health analyses of 5% Medicare Standard Analytic Files; CBO April 2014 Medicare Baseline; 2013 Medicare Trustees’ Report.
NOTES


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