



# Medicare Immunosuppressive Drug Coverage for Kidney Transplant Recipients

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## Summary

End-stage renal disease (ESRD) is substantial and permanent loss in kidney function. Persons with ESRD require either a regular course of dialysis treatment (a process that removes harmful waste products from an individual's blood stream) or a kidney transplant to survive. The Medicare program provides coverage for health care services for the vast majority of individuals diagnosed with ESRD, regardless of age.

In 2010, roughly 489,000 Medicare beneficiaries received ESRD-related services—less than 1% of the total Medicare population. According to the United States Renal Data System (USRDS), in 2010, Medicare expenditures for the ESRD-related services totaled \$32.9 billion, or roughly 6.3% of total Medicare expenditures.

The Medicare program consists of four parts: Part A (Hospital Insurance, or HI), Part B (Supplementary Medical Insurance, or SMI), Part C (Medicare Advantage), and Part D (outpatient prescription drug coverage). Under Part A, Medicare-covered ESRD-related services include dialysis treatments upon admission to a hospital, inpatient services in an approved hospital for covered kidney transplants, and the cost of care for the individual donating a kidney. Under Part B, Medicare-covered ESRD-related services include dialysis treatments in a dialysis facility or at home, physicians' services for kidney transplant procedures, and certain prescription drugs—including immunosuppressive drugs (for individuals who received a Medicare-covered transplant). Under Part D, beneficiaries can also enroll in a prescription drug plan to receive coverage for drugs that treat ESRD-related symptoms and any additional outpatient prescription drugs. Coverage of immunosuppressive drugs for individuals whose transplant was not covered by Medicare may be covered under Part D.

Individuals who have received a kidney transplant usually require immunosuppressive drugs for the rest of their life to minimize the risk of their immune system rejecting the donor kidney. In 2010, Part B expenditures for immunosuppressive drugs totaled \$345 million. Under Part B, Medicare provides payment for immunosuppressive drugs based on manufacturers' reported average sales price (ASP), for each drug, plus a 6% handling and storage payment. Since 2009, the ASP for commonly used immunosuppressive drugs has decreased by over 50%—most likely due to the use of generics.

For ESRD beneficiaries, Medicare covers a lifetime of dialysis treatments. For Medicare-eligible individuals with a functioning kidney transplant, Medicare covers the cost of the transplant and 36 months of follow-up care (which includes immunosuppressive medication). According to the USRDS, at the end of 2010, approximately 41% of individuals under the age of 65 who had a functioning kidney transplant and thus no longer required dialysis were not covered by Medicare. Since the 105<sup>th</sup> Congress, legislation has been introduced in each Congress to provide some form of Medicare coverage for post-transplant recipients who are no longer entitled to Medicare following 36 months of a successful kidney transplant. Individuals who are not covered by Medicare who require immunosuppressive drugs and do not have health insurance may have to pay the cost of immunosuppressive drugs out-of-pocket. In 2014, individuals who are not covered by Medicare and who have a functioning kidney transplant may have greater access to immunosuppressive drug coverage from private health plans due to provisions in the Patient Protection and Affordable Care Act and a recent decline in the price of commonly used immunosuppressive drugs.

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## **ESRD and Medicare Eligibility**

End-stage renal disease (ESRD) is the final phase of chronic kidney disease—a gradual loss in kidney function over time. In the final phase of chronic kidney disease, the loss in kidney function appears irreversible and a regular course of dialysis treatments (approximately three times a week) is needed to survive.<sup>1</sup> A kidney transplant procedure, whereby an individual receives a healthy donor kidney to replace a non-functioning kidney, is an alternative form of treatment. After undergoing a kidney transplant, patients are usually required to take immunosuppressive drugs for the rest of their life to minimize the risk of their immune system rejecting the donor kidney.

Medicare is a federal program that pays for covered health care services, which include kidney transplantation for eligible beneficiaries. Generally, individuals are eligible for Medicare if they are at least 65 years old, a citizen or permanent resident of the United States, and have met the prior work requirements.<sup>2</sup> Individuals may also be eligible to enroll in Medicare under the age of 65 if they are permanently disabled and receive disability benefits from Social Security (or the Railroad Retirement Board). With the passage of the Social Security Amendments of 1972 (P.L. 92-603), Medicare provides coverage for certain individuals who are diagnosed with ESRD.<sup>3</sup> Specifically, an individual medically determined to have ESRD can be eligible to enroll in Medicare if he or she, or his or her spouse, parent, or guardian, has earned at least six Social Security credits over the past three years.<sup>4</sup> Originally, for ESRD beneficiaries, Medicare eligibility was limited to 12 months following a successful kidney transplant (if the individual no longer required dialysis). The 12 months of post-transplant Medicare eligibility was extended to 36 months with the passage of P.L. 95-292 in 1978.

For beneficiaries who are eligible for Medicare due to ESRD, Medicare may provide coverage on the first month of eligibility if the beneficiary is admitted to a Medicare-approved hospital to undergo a kidney transplant procedure or elects to receive dialysis treatment at home. For beneficiaries who do not elect to receive dialysis at home, Medicare coverage begins on the fourth month of receiving dialysis treatment. With few exceptions, Medicare is a secondary payer for the first 30 months of eligibility for beneficiaries who become entitled to Medicare due to ESRD and are insured under a union or employer-sponsored health plan.

## **Medicare Coverage of ESRD-Related Services**

Medicare consists of four distinct parts: Part A (Hospital Insurance, or HI), Part B (Supplementary Medical Insurance, or SMI), Part C (Medicare Advantage), and Part D

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<sup>1</sup> Dialysis treatment is a process of filtering an individual's blood with a fluid solution (dialysate) thereby removing harmful wastes, a process otherwise performed by functioning kidneys.

<sup>2</sup> Individuals (their spouses and, in some cases, their dependents) are eligible for premium-free Medicare Part A if they earned at least 40 credits in Medicare-covered employment.

<sup>3</sup> Social Security Act §226A.

<sup>4</sup> A Social Security credit (or "quarter of coverage") is a dollar amount of covered earnings that changes every year per a statutory formula based on average wage growth. A worker can earn up to four credits a year. In 2013, one Social Security credit is \$1,160 of earnings in one year.

(outpatient prescription drugs).<sup>5</sup> Individuals who are entitled to Medicare Part A are able to receive coverage primarily for inpatient hospital services, post-hospital services, and hospice services. Beneficiaries entitled to Part A have the option of enrolling in Medicare Part B, which provides coverage for physicians and nonphysician practitioner services, durable medical equipment, certain specified outpatient prescription drugs and biologics (e.g., immunosuppressive drugs for covered-transplant beneficiaries), and hospital outpatient services, in addition to other services. Together, Medicare Parts A and B represent “original” Medicare or Medicare fee-for-service (FFS). Part C, Medicare Advantage (MA), is an alternative way for beneficiaries to receive covered services. Under MA, private health plans are paid a per-person amount to provide all covered services under Parts A and B (except hospice).<sup>6</sup> Beneficiaries entitled to Part A and/or enrolled in Part B may also enroll in Medicare Part D to receive coverage of outpatient prescription drugs. Under Part D, prescription drug coverage is provided through private stand-alone prescription drug plans or through MA drug plans (MA health plans, which also include prescription drug coverage).

Upon Medicare eligibility due to ESRD, a beneficiary is enrolled in Medicare Parts A and B; however, a beneficiary may decline Part B coverage. For ESRD-related services, Medicare Part A includes coverage for inpatient services in an approved hospital for covered kidney transplants and cost of care for the kidney donor.<sup>7</sup> Medicare Part B provides coverage for doctors’ services during a kidney transplant, outpatient dialysis treatments, and related services in a Medicare-certified dialysis facility or in a beneficiary’s home. Part B also provides coverage of immunosuppressive drugs for individuals who had a Medicare-covered transplant to minimize the risk of kidney rejection, in addition to specified drugs/biologics (e.g., erythropoietin stimulating agents used to treat anemia).

According to the United States Renal Data System (USRDS), in 2010, total Medicare expenditures for beneficiaries with ESRD were estimated to be \$32.9 billion, or roughly 6.3% of total Medicare expenditures.<sup>8</sup> Part B immunosuppressive drug expenditures consisted of \$345 million in 2010. Further, the USRDS estimated annual per beneficiary Medicare expenditures in 2010 to be \$87,561 for a beneficiary receiving hemodialysis (the most common form of dialysis treatment) and \$32,914 for a beneficiary with a functioning kidney transplant.

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<sup>5</sup> For more information on the distinct parts of Medicare, see CRS Report CRS Report R40425, *Medicare Primer*, coordinated by (name redacted) and (name redacted).

<sup>6</sup> ESRD beneficiaries may be able to enroll in an MA plan if (1) they were already in an MA plan when they were diagnosed with ESRD; (2) their employer-sponsored plan offers an MA plan; (3) they have had a successful Medicare-covered kidney transplant; or (4) there is a Medicare Special Needs Plan (SNP) available in their area.

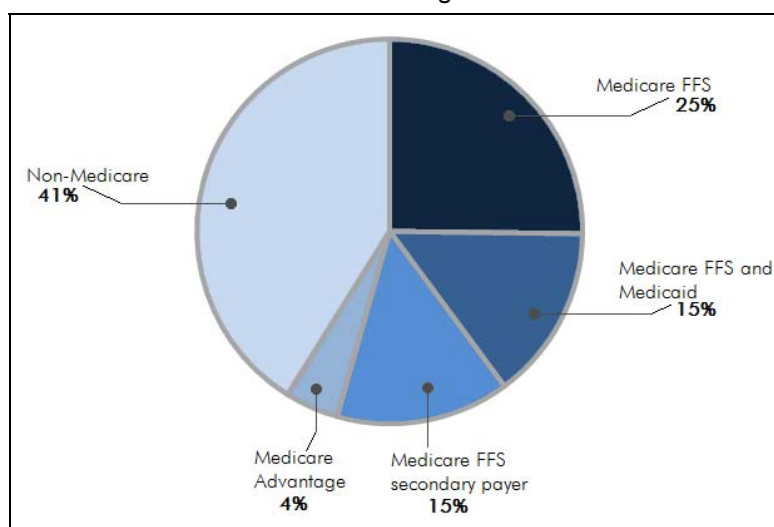
<sup>7</sup> Only certain qualifying hospitals can provide Medicare-covered transplant procedures.

<sup>8</sup> US Renal Data System, *USRDS 2012 Annual Data Report: Atlas of Chronic Kidney Disease and End-Stage Renal Disease in the United States*, Bethesda, MD, 2012, p. 168, <http://www.usrds.org/2012/slides/indiv/v2index.html>. USRDS is a national data registry that collects, analyzes, and distributes information on the ESRD population in the United States. This organization is funded by the National Institutes of Health. According to Table V.B.1 of the *2013 Annual Report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds*, total Medicare expenditures in 2010 were \$522.9 billion.

## Limitations of Medicare Eligibility for ESRD Beneficiaries

As of December 31, 2010, according to USRDS, roughly 489,000 individuals were estimated to be diagnosed with ESRD and were eligible for some form of Medicare coverage.<sup>9</sup> For beneficiaries who qualify for Medicare due to ESRD, Medicare eligibility is limited to 36 months following a successful kidney transplant.<sup>10</sup> Of the individuals under the age of 65 that have received a successful kidney transplant at a prior date and no longer required dialysis treatment in 2010 (142,923 patients), roughly 41% were not eligible for Medicare coverage (58,728 patients); see **Figure 1**.<sup>11</sup> Roughly 25% of patients under the age of 65 were covered under original Medicare, and an additional 15% were covered under both Medicare and Medicaid.<sup>12</sup> An additional 15% of individuals under the age of 65 who received a kidney transplant had Medicare as a secondary payer and 4% were enrolled in an MA plan.<sup>13</sup>

**Figure 1. USRDS Estimate of Kidney Transplant Recipient's Source of Insurance**  
Individuals Under the Age of 65 in 2010



**Source:** US Renal Data System, *USRDS 2012 Annual Data Report: Atlas of Chronic Kidney Disease and End-Stage Renal Disease in the United States*, Bethesda, MD, 2012, Table D.24, <http://www.usrds.org/reference.aspx>.

**Note:** FFS (fee-for-service). Non-Medicare includes beneficiaries who are insured under Medicaid, private health insurance, or who do not have health insurance.

<sup>9</sup> US Renal Data System, *USRDS 2012 Annual Data Report: Atlas of Chronic Kidney Disease and End-Stage Renal Disease in the United States*, Bethesda, MD, 2012, Table D.21, <http://www.usrds.org/reference.aspx>.

<sup>10</sup> There is no time limitation of Medicare coverage if a beneficiary requires dialysis treatment.

<sup>11</sup> US Renal Data System, *USRDS 2012 Annual Data Report: Atlas of Chronic Kidney Disease and End-Stage Renal Disease in the United States*, Bethesda, MD, 2012, Table D.24, <http://www.usrds.org/reference.aspx>.

<sup>12</sup> For individuals enrolled in both Medicare and Medicaid, also known as “dual eligibles,” Medicare would be the primary payer for drugs and services covered under both Medicare and Medicaid.

<sup>13</sup> For more information on Medicare as a secondary payer for individuals with ESRD, see CRS Report RL33587, *Medicare Secondary Payer: Coordination of Benefits*, by (name redacted) and (name redacted).

## Medicare Coverage of Immunosuppressive Drugs for Kidney Transplant Recipients

Individuals with a functioning kidney transplant usually require immunosuppressive drugs for life to minimize the risk of their immune system rejecting the “foreign” donor kidney.<sup>14</sup> For the most part, the standard of care for immunosuppressant therapy in kidney transplant recipients is a combination of a calcineurin inhibitor and an antimetabolite (with or without a corticosteroid).<sup>15</sup> The most commonly prescribed calcineurin inhibitor is a daily dose of tacrolimus, and the more commonly prescribed antimetabolite is a daily dose of mycophenolate mofetil (MMF). The first generic of tacrolimus was approved in 2009, and generics for MMF were approved in 2008. In addition to tacrolimus and MMF, other prescribed immunosuppressants may include azathioprine, cyclosporine, mycophenolic sodium, prednisone, and sirolimus.<sup>16</sup>

Currently, Medicare provides coverage for immunosuppressive drugs under Part B if the transplant was covered by Medicare and in an approved facility. Medicare Part B does not provide coverage for immunosuppressive drugs if the beneficiary was not eligible for Medicare at the time of the transplant or the transplant was not in a Medicare-covered facility.<sup>17</sup> Medicare first allowed coverage of immunosuppressive drugs under Part B to beneficiaries following a Medicare-covered organ transplant in a Medicare-approved facility in 1987, with the passage of the Omnibus Budget Reconciliation Act of 1986 (OBRA 86; P.L. 99-509).<sup>18</sup> OBRA 86 limited Medicare immunosuppressive drug coverage for all beneficiaries to 12 months following an organ transplant. The 12-month time limitation may have been included because, according to a committee report referenced in the House’s FY1986 budget resolution report, there was already “a significant amount of insurance coverage for immunosuppressive drugs available” for individuals with ESRD.<sup>19</sup>

Under the Omnibus Budget Reconciliation Act of 1993 (P.L. 103-66), immunosuppressive drug coverage for beneficiaries who received an organ transplant was gradually extended from 12 months following a covered transplant to 36 months beginning on January 1, 1998, and subsequent years. The Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (P.L. 106-554) eliminated the 36-month time limitation of immunosuppressive drug coverage after covered kidney transplants. While Medicare coverage of immunosuppressive drugs is no longer time-limited, for beneficiaries who qualified for Medicare due to ESRD, Medicare

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<sup>14</sup> A recent study showed success in avoiding the need for immunosuppressive drugs following kidney transplantation. For more information, see Joseph Leventhal et al., “Chimerism and Tolerance Without GVHD or Engraftment Syndrome in HLA-Mismatched Combined Kidney and Hematopoietic Stem Cell Transplantation,” *Science Translational Medicine*, vol. 4, no. 124 (March 7, 2012).

<sup>15</sup> Peter Chung-Wen Chang and Donald E. Hricik, “What Are Immunosuppressive Medications? How Do They Work? What Are Their Side Effects?,” in *Kidney Transplantation: A Guide to the Care of Kidney Transplant Recipients*, ed. Dianne B. McKay, Steven M. Steinberg (New York: Springer, 2010), p. 132.

<sup>16</sup> Centers of Medicare & Medicaid Services, *Medicare Benefit Policy Manual*, Chapter 15 Section 50.5.1.

<sup>17</sup> Beneficiaries entitled to Part A who were not eligible for Medicare at the time of the transplant or did not receive the transplant in a Medicare-approved facility may still receive coverage for immunosuppressive drugs by enrolling in a Part D prescription drug plan

<sup>18</sup> Social Security Act §1861(s)(2)(J).

<sup>19</sup> U.S. Congress, House Committee on Energy and Commerce, Subcommittee on Health and Environment, *Organ Transplants*, 98<sup>th</sup> Cong., 2<sup>nd</sup> sess., May 15, 1984, H.Rept. 98-769, p. 12.

eligibility (and therefore Medicare immunosuppressive drug coverage) is still limited to 36 months following a successful kidney transplant if they do not qualify for Medicare due to age (65 years or older) or disability (generally, a Social Security Disability Insurance recipient).<sup>20</sup> After 36 months, the individual is no longer eligible for Medicare, and must find some other form of payment for the immunosuppressive drugs (e.g., private insurance, out-of-pocket).<sup>21</sup> Individuals who are unable to adhere to their medication regimen, possibly due to the costs of immunosuppressive drugs, may cause their donor kidney to fail.

In 2007, the Government Accountability Office (GAO) found that the percentage of beneficiaries whose kidney transplants failed roughly doubled when increasing the timeframe from 36 months following the transplant to seven years.<sup>22</sup> While continuity of insurance coverage may affect a beneficiary's access to immunosuppressive drugs, insurance coverage alone may not be the sole contributing factor to failed kidney transplants. In addition, GAO notes in its report, “(w)hile a lack of health insurance is one reason transplant recipients may stop taking their medication, studies have reported that there are numerous other reasons for medication noncompliance, including avoidance of adverse side effects associated with immunosuppressive medications and difficulty following complex treatment regimens.”

Beginning January 1, 2014, beneficiaries with a functioning kidney transplant who are no longer entitled to Medicare may have greater access to health insurance in the private market (and therefore potential coverage of immunosuppressive drugs), due to provisions in the Patient Protection and Affordable Care Act (ACA, P.L. 111-148, as amended) that prohibit excluding coverage for preexisting conditions and pricing health insurance premiums based on health factors. While there is no adequate estimate of the percentage of private health plans that currently offer immunosuppressive coverage, a non-random selective sample of publically available prescription drug formularies among health plans offered by a number of large health insurers suggests that the more commonly used immunosuppressive drugs by individuals with ESRD are often covered.<sup>23</sup>

Further, beginning in 2014, ACA requires private health plans offered through the new health insurance exchanges to cover essential health benefits (EHB), which are based on a state-specific benchmark health plan.<sup>24</sup> Based on the preliminary 2012 EHB-benchmark plan designs across all states, each state would require health plans offered in the exchanges to cover drugs in the “immunosuppressive agent” class.<sup>25</sup> State EHB-benchmark plans vary between requiring at least

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<sup>20</sup> Social Security Act §226A(b)(2).

<sup>21</sup> Medicare coverage may resume if an individual's donor kidney fails and the patient requires dialysis treatment.

<sup>22</sup> United States Government Accountability Office, *End-Stage Renal Disease: Characteristics of Kidney Transplant Recipients, Frequency of Transplant Failures, and Cost to Medicare*, September 2007, p. 16, <http://www.gao.gov/assets/270/267345.pdf>.

<sup>23</sup> The study sample included drug formularies from private health plans offered by Aetna, Anthem, Blue Cross Blue Shield of Michigan, Blue Cross Blue Shield of North Carolina, Cigna, Kaiser Permanente, United Healthcare, CVS Caremark, and Express Scripts. Coverage information for tacrolimus and MMF described in available health plans was obtained through an Internet search.

<sup>24</sup> A health insurance exchange is a structured marketplace for the sale and purchase of health insurance. For more information on health insurance exchanges, see CRS Report R42663, *Health Insurance Exchanges Under the Patient Protection and Affordable Care Act (ACA)*, by (name redacted) and (name redacted).

<sup>25</sup> State-specific EHB-benchmark plans were based on 2012 plan designs, and include state-required benefits that were enacted before December 31, 2011. These preliminary plan designs may not reflect requirements effective for plan years starting on or after January 1, 2014.



3 and as many as 24 different immunosuppressive drug products, but roughly half of all states would require at least 20 different immunosuppressive drug products to be covered in health plans offered through their state's health insurance exchange. The total number of drug products in the immunosuppressive agent class may not be much larger than 20, which may suggest that, in states that require a large number of immunosuppressive drug products to be covered, health plans offered in these exchanges would cover immunosuppressive drugs commonly used by transplant recipients.<sup>26</sup>

## Medicare Payment Policy of Immunosuppressive Drugs for Kidney Transplant Recipients

### Part B Payment Policy of Immunosuppressive Drugs

In most cases, for individuals who have received a Medicare-covered organ transplant, Medicare Part B will provide coverage of immunosuppressive drugs for beneficiaries who choose to enroll in Part B. Beginning in 2005, Medicare's Part B drug payment methodology is based on manufacturers' reported average sales price (ASP) for each drug, plus a 6% handling and storage payment. For covered Part B drugs, beneficiaries are responsible for a 20% coinsurance in addition to the annual Part B deductible (\$147 in 2013).

In 2010, Medicare Part B immunosuppressive drug expenditures (which included expenditures for beneficiaries who received other types of organ transplants) totaled \$345 million, growing at an average annual rate of 8% since 2005, when the new payment methodology (ASP plus an acquisition add-on) for Part B covered drugs went into effect.<sup>27</sup> In comparison, between 2005 and 2010, Medicare payments for Part B covered drugs that were administered in physicians' offices or furnished by suppliers increased at an average annual rate of roughly 2.6%.<sup>28</sup> According to the USRDS, in 2010, Medicare expenditures for Part B immunosuppressive drugs were \$4,008 per transplant recipient.<sup>29</sup>

Roughly 85% of post-transplant beneficiaries use a combination of tacrolimus and MMF or tacrolimus and mycophenolic sodium (MPS, also known as Myfortic).<sup>30</sup> In 2010, the largest Medicare Part B immunosuppressive drug expenditure, as well as the most frequently billed for

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<sup>26</sup> For more information on the EHB prescription drug coverage methodology, see <http://www.cms.gov/CCIIO/Resources/Data-Resources/Downloads/ehb-rx-crosswalk.pdf>. An estimate of the total numbers of immune suppressant drug products available is 21. This estimate was gathered from the CMS Formulary Reference File Alignment File by grouping unique identifiers (RXCUIs) with the same active ingredient.

<sup>27</sup> *USRDS 2012 Annual Data Report: Atlas of Chronic Kidney Disease and End-Stage Renal Disease in the United States*, Bethesda, MD, 2012, Table K.b, <http://www.usrds.org/reference.aspx>.

<sup>28</sup> Medicare Payment Advisory Commission, *A Data Book: Health Care Spending And The Medicare Program*, Washington, DC, June 2012, p. 157, <http://www.medpac.gov/documents/Jun12DataBookEntireReport.pdf>.

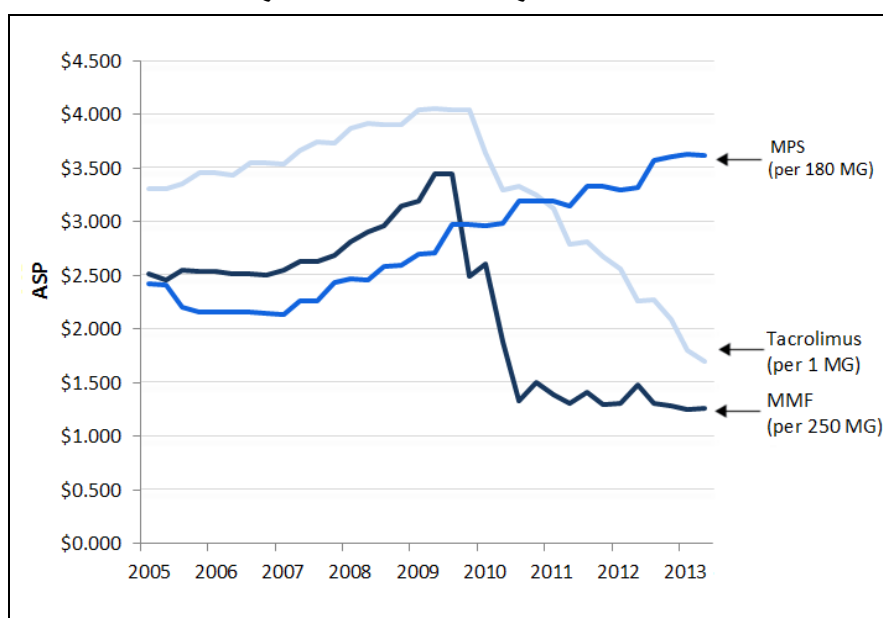
<sup>29</sup> US Renal Data System, *USRDS 2012 Annual Data Report: Atlas of Chronic Kidney Disease and End-Stage Renal Disease in the United States*, Bethesda, MD, 2012, Table K.b, <http://www.usrds.org/reference.aspx>. This figure is for individuals with Medicare as a primary payer only.

<sup>30</sup> Health Resources and Services Administration, *OPTN & SRTR Annual Data Report 2011*, December 2012, p. 36, [http://srtr.transplant.hrsa.gov/annual\\_reports/2011/pdf/2011\\_SRTR\\_ADR.pdf](http://srtr.transplant.hrsa.gov/annual_reports/2011/pdf/2011_SRTR_ADR.pdf).

immunosuppressive drug, was tacrolimus—which totaled \$200 million.<sup>31</sup> Between 2005 and 2010, Part B payments for tacrolimus grew at an average annual rate of 11.2%. The increase in tacrolimus expenditures was driven by an average annual growth rate of 10.8% in claims filed—from 46.6 million Part B claims filed in 2005 to roughly 78.1 million in 2010. Despite the large rise in utilization of tacrolimus, Part B expenditures for tacrolimus have been otherwise moderated by a decline in the ASP, which may be attributed to competition from tacrolimus generics (see **Figure 2**).

MMF is the second most frequently billed Part B immunosuppressive drug, which totaled roughly \$85 million in 2010.<sup>32</sup> Between 2005 and 2010, the average rate of growth in Part B expenditures for MMF declined by 1.2%. This could be attributed to the large decline in the ASP of MMF in 2010 and the rise in utilization of MPS (from 2.2 million claims filed in 2005 to 23.9 million in 2010).<sup>33</sup> MPS functions similarly as MMF and was approved for sale by the FDA in 2004. Part B expenditures for MPS have grown rapidly (from \$4 million in 2005 to \$56 million in 2010) due to the rise in MPS utilization as well as a steady increase in the ASP of MPS since 2007, as shown in **Figure 2**.

**Figure 2. Medicare Part B Average Sales Price (ASP) for MMF, MPS, and Tacrolimus**  
1<sup>st</sup> Quarter of 2005 to 2<sup>nd</sup> Quarter of 2013



**Source:** CRS analysis of reported Medicare Part B ASP data available at <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/McrPartBDrugAvgSalesPrice/index.html>.

**Notes:** The Part B ASP for tacrolimus and MMF reflect sales of the brand name drug as well as any generic equivalent. As of July 2013, there are no generic equivalents for MPS.

<sup>31</sup> CRS analysis of Medicare Part B tacrolimus expenditures and claims filed (Healthcare Common Procedure Coding System code J7507) were extracted from the Part B National Summary Data File for years 2005 to 2010.

<sup>32</sup> CRS analysis of Medicare Part B MMF expenditures and claims filed (Healthcare Common Procedure Coding System code J7517) were extracted from the Part B National Summary Data File for years 2005 to 2010.

<sup>33</sup> CRS analysis of Medicare Part B MPS expenditures and claims filed (Healthcare Common Procedure Coding System code J7518) were extracted from the Part B National Summary Data File for years 2005 to 2010.

## Part D Payment Policy of Immunosuppressive Drugs

Beneficiaries enrolled in Medicare Part D can receive coverage for any additional outpatient prescription drugs and/or for immunosuppressive drugs if the transplant was not covered by Medicare. Medicare Part D will not provide immunosuppressive drug coverage for beneficiaries who have received a Medicare-covered transplant regardless if the beneficiary is enrolled in Part B and/or Part D. Payment for drugs is determined by the prescription drug plan and cost-sharing amounts for covered drugs vary by plan; however, in general, prescription drug plans have lower cost-sharing amounts for generics compared to brand name drugs.

## Issue for Congress

Some experts have noted that limiting Medicare coverage to 36 months after a successful covered kidney transplant for beneficiaries entitled on the basis of ESRD may be counterproductive.<sup>34</sup> Some beneficiaries may not be able to afford immunosuppressive medication on an out-of-pocket basis. Transplant recipients who do not adhere to their prescribed immunosuppressive medication could cause their donor kidneys to fail and thus require a much more expensive dialysis treatment for their ESRD or they may need another transplant. The 36-month time limitation may adversely affect beneficiaries' health status and quality of life. While beneficiaries with ESRD who received a functioning kidney transplant no longer require dialysis treatment to survive, such individuals are not considered "cured" of the disease—instead requiring immunosuppressant therapy rather than dialysis as a form of treatment.<sup>35</sup>

Since the 105<sup>th</sup> Congress, legislation has been introduced in each Congress to extend some form of Medicare coverage after the 36 months following a kidney transplant for individuals who are not otherwise eligible to enroll in Medicare. Most recently, S. 323 and H.R. 1428 were introduced in the 113<sup>th</sup> Congress to provide Medicare Part B as a secondary payer of only immunosuppressive drugs for kidney transplant recipients who are no longer eligible for Medicare coverage and are enrolled in a group health plan (i.e., a health plan contributed to by an employer or employee organization) beginning January 1, 2014. Under these proposals, Medicare would be the primary payer of immunosuppressive drugs for individuals who are not enrolled in a group health plan (i.e., purchase an individual health plan in the private market).<sup>36</sup> Individuals who would be eligible to enroll in Part B for only immunosuppressive drug coverage would pay a slightly lower monthly Part B premium than the standard monthly premium (\$104.90 in 2013).

In addition, in 2014, individuals with a functioning kidney transplant may have greater access to immunosuppressive drug coverage from private health plans in the individual and small business marketplace. A number of factors that could have a positive impact for individuals looking to obtain immunosuppressive drug coverage include (1) ACA provisions that prohibit excluding

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<sup>34</sup> Committee on Medicare Extensions, *Extending Medicare Coverage for Preventive and Other Services*, Institute of Medicine, Washington, DC, 2000, pp. 99-126.

<sup>35</sup> National Institute of Diabetes and Digestive and Kidney Diseases, *Treatment Methods for Kidney Failure: Transplantation*, National Institutes of Health, May 2006, p. 1, [http://kidney.niddk.nih.gov/kudiseases/pubs/transplant/transplant\\_508.pdf](http://kidney.niddk.nih.gov/kudiseases/pubs/transplant/transplant_508.pdf).

<sup>36</sup> In 2014, ACA through amendments to the Internal Revenue Code requires individuals to maintain minimum essential health insurance coverage, with some exceptions. Enrollment in Part B for solely immunosuppressive drug coverage would not meet the criteria of minimum essential coverage.

coverage for preexisting conditions and pricing health insurance premiums on health factors, (2) the preliminary 2012 state EHB-benchmark plans, which require some coverage of immunosuppressive drugs in the new health insurance exchanges, and (3) a recent decline in the price of commonly used immunosuppressive drugs (tacrolimus and MMF).

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