



MEDICARE PART B DRUG PAYMENTS IMPLICATED IN CMMI MODELS

In response to growing public attention on the cost of prescription drugs, policymakers have proposed drug pricing reforms that could affect medical benefit drugs covered under Medicare Part B. The Medicare Payment Advisory Commission's (MedPAC) June 2015 and June 2016 reports each included a chapter dedicated to the exploration of how Medicare pays for Part B drugs and oncology services.^{1,2} Spending for Part B drugs also has been a recent focus within the Center for Medicare & Medicaid Innovation (CMMI). In March 2016, CMMI proposed a mandatory demonstration program that modifies the Medicare Part B drug reimbursement formula.^{3,4}

CMMI also has addressed Part B expenditures more broadly through a variety of programs currently being tested and implemented across Medicare. The programs seek to incentivize providers to reduce spending and improve the value of health care services, including Medicare Part B drugs. This brief examines these programs, which place providers at risk for Medicare spending, and how they may motivate providers to manage Medicare Part B costs, including drug spending and utilization. The models considered include the Bundled Payments for Care Improvement (BPCI) initiative, Comprehensive Care for Joint Replacement (CJR) model, Comprehensive ESRD Care (CEC) model, Oncology Care Model (OCM), Medicare Shared Savings Program (MSSP), Next Generation Accountable Care Organization (ACO) model, and Pioneer ACO model.

CMMI's evaluation of these programs and their impact on spending, including spending on Part B drugs, can inform the direction of future Medicare policy.

Episode Payment Models (EPMs)

Bundled Payments for Care Improvement (BPCI) Initiative and the Comprehensive Care for Joint Replacement Model (CJR)

The voluntary BPCI demonstration and the mandatory CJR model introduce incentives to reduce Part B expenditures by holding providers accountable for all costs over an extended episode of care. These models require provider participants to bear risk for total Medicare Part A and Part B expenditures beginning with a hospital stay and covering a defined period of time. Participants receive a target price based on historical Medicare expenditures and are financially responsible for spending above the target. Spending below the target results in payment from CMS to the participant. Participants have the option to share gains (under both programs) and losses (under CJR) with provider partners treating patients within their episodes. The broad nature of financial risk within these programs gives provider participants and

-
- 1 June 2015 Report to Congress: Medicare and the Health Care Delivery System. MedPAC. Available at: <http://www.medpac.gov/docs/default-source/reports/june-2015-report-to-the-congress-medicare-and-the-health-care-delivery-system.pdf?sfvrsn=0>.
 - 2 June 2016 Report to Congress: Medicare and the Health Care Delivery System. MedPAC. Available at: <http://www.medpac.gov/docs/default-source/reports/june-2016-report-to-the-congress-medicare-and-the-health-care-delivery-system.pdf?sfvrsn=0>.
 - 3 The Affordable Care Act (ACA) established CMMI to design and test innovative payment and delivery models to reduce costs while maintaining or improving the quality of care for beneficiaries. The ACA appropriated \$10B to support CMMI's activities initiated from 2011 to 2019. Following formal evaluation and subject to meeting actuarial standards, the Secretary of the U.S. Department of Health and Human Services (HHS) may expand the duration and scope of successful models developed and tested by CMMI. Source: Social Security Act § 1115A [42 U.S.C. § 1315a].
 - 4 The Part B Drug Payment Model would test whether alternative drug payment designs will lead to a reduction in Medicare Part B expenditures, while preserving or enhancing quality of care for beneficiaries. Medicare Part B drug payment is directly implicated through the first phase of the proposed model in which Medicare seeks to adjust the six percent add-on payment of the Average Sales Price (ASP) methodology to minimize provider incentives to use higher cost drugs. Source: Medicare Program; Part B Drug Payment Model, 81 Fed. Reg. 13230 (proposed Mar. 11, 2016) (to be codified at 42 CFR Part 511).



their partners direct incentive to reduce expenditures across a variety of Medicare services, including Part B drugs.^{5,6}

CMMI has demonstrated a commitment to expand the scope of episodic payment models, and these programs already cover a significant reach of Medicare providers and services. BPCI began on a voluntary basis in 2013 and now includes over 1,300 risk-bearing hospitals, physician groups, and post-acute care providers nationally. BPCI participants selected from 48 clinical conditions for risk-bearing over 30-, 60-, or 90-day episode periods. The 48 Medicare Severity Diagnosis-Related Group (MS-DRG)-based clinical conditions in BPCI represent approximately 85% of all Medicare fee-for-service (FFS) hospital discharges, and participants were more likely to choose higher-volume clinical conditions among the 48 for risk-bearing.⁷ CJR was implemented on a mandatory basis for all hospitals in 67 Metropolitan Statistical Areas (MSAs) beginning on April 1, 2016. CMS excluded CJR-specific MSAs with high BPCI participation in order to expand the geographic diversity of episode-based payment models.⁸ CJR covers major joint replacement of the lower extremity (MS-DRGs 469 and 470) episodes including the initial hospital stay plus 90-days post-discharge, and a recent proposal would expand the program to include non-joint replacement surgical hip/femur treatment procedures (MS-DRGs 480-482).^{9,10}

Oncology Care Model (OCM)

OCM is a voluntary CMMI demonstration that aims to encourage better care coordination and reduce the total cost of chemotherapy treatment by holding oncologists accountable to spending for a 6-month chemotherapy episode. Participating providers receive a fixed monthly payment for the management and coordination of the beneficiary's cancer care during the episode, and would be eligible for incentives based on the total cost of care during the episode for eligible cancer diagnoses. OCM episodes initiate based on either a Medicare Part B chemotherapy claim with an eligible cancer diagnosis administered outside of the inpatient hospital, or a Medicare Part D chemotherapy drug claim with a corresponding Part B claim with an eligible cancer diagnosis. All Medicare Parts A and B spending are included in the six-month OCM episode, in addition to certain Medicare Part D expenditures. CMS has created specific protections related to new therapies. CMS will provide payment adjustments to account for the use of novel oncology therapies, including Part B and Part D drugs receiving FDA approval in 2015 or later. CMS developed this mechanism to mitigate the potential disincentive that OCM participating providers would have to use new and costly therapies while at risk for total Medicare payments.

The extent to which this program will influence physician behaviors around chemotherapies is still unknown, but the program will continue to pressure practices to reduce expenditures across a variety of services, including Part B and Part D drugs. The broad incentives around total cost of care within OCM could change the way physician practices evaluate outcomes and the value of treatments, including Part B therapy.¹¹

5 Bundled Payments for Care Improvement (BPCI) Initiative. CMS. Available at: <https://innovation.cms.gov/initiatives/bundled-payments/>.

6 Comprehensive Care for Joint Replacement Model. CMS. Available at: <https://innovation.cms.gov/initiatives/CJR>.

7 Bundled Payments for Care Improvement (BPCI) Initiative. CMS. Available at: <https://innovation.cms.gov/initiatives/bundled-payments/>.

8 Medicare Program; Comprehensive Care for Joint Replacement Model for Acute Care Hospitals Furnishing Lower Extremity Joint Replacement Services, 80 Fed. Reg. 73273, 73292 (Nov. 24, 2015) (codified at 42 CFR Part 510). Available at: <https://www.gpo.gov/fdsys/pkg/FR-2015-11-24/pdf/2015-29438.pdf>.

9 Comprehensive Care for Joint Replacement Model. CMS. Available at: <https://innovation.cms.gov/initiatives/CJR>.

10 CMMI has further demonstrated its commitment to expanding the scope of episodic payment models in its July 2016 announcement of three new proposed mandatory bundled payment models. The proposed models require hospitals to bear financial risk for the total cost of the inpatient stay and 90 days of post-discharge care for acute myocardial infarction (AMI), coronary artery bypass graft (CABG), or surgical hip/femur fracture treatment (SHFFT) episodes. Source: Medicare Program; Advancing Care Coordination Through Episode Payment Models (EPMs); Cardiac Rehabilitation Incentive Payment Model; and Changes to the Comprehensive Care for Joint Replacement Model (CJR), 81 Fed. Reg. 50794 (proposed Aug. 2, 2016) (to be codified at 42 CFR Parts 510 and 512).

11 Oncology Care Model. CMS. Available at: <https://innovation.cms.gov/initiatives/oncology-care/>.

Disease-Specific Model

Comprehensive ESRD Care (CEC) Model

The CEC Model is a voluntary CMMI program, set to begin in 2017, through which dialysis clinics, nephrologists and other providers join together to create an End Stage Renal Disease (ESRD)-focused ACO to coordinate care for Medicare beneficiaries. CMMI is testing whether comprehensive medical management and care coordination will result in improved outcomes and savings among ESRD beneficiaries, who are often excluded from CMMI demonstrations. Participants in this model are accountable for total Medicare Parts A and B spending on a Per-Beneficiary-Per-Year basis, including spending for dialysis, where each performance year is compared to a risk-adjusted and trended historical baseline per-capita expenditure amount.^{12,13} Spending on physician services, durable medical equipment (DME), and Part B drugs are included in the total Medicare Part B spending component, implicating Part B drug spending and utilization.¹⁴ CEC model participants are still subject to the ESRD Prospective Payment System (PPS) which is designed specifically to manage drug costs for these types of patients.

Accountable Care Organizations (ACOs)

Medicare Shared Savings Program (MSSP) ACOs

The MSSP is a nationwide program created by the ACA. Health care providers and suppliers join together to form ACOs, which seek to reduce Medicare spending and increase quality by coordinating care for fee-for-service beneficiaries. ACOs may choose either an upside-only or downside-risk model. Under the MSSP's upside-only model, or Track 1, an ACO can share in savings that accrue to the Medicare program provided quality and spending benchmarks are met. Downside-risk ACOs (MSSP Tracks 2 or 3) are eligible for greater shared savings than Track 1, but may be required to repay losses to the Medicare program if spending exceeds the applicable benchmark threshold.

MSSP ACOs are held accountable to a benchmark spending threshold established by CMS based on the ACO's historic Medicare Parts A and B spending, including Part B drug spending, for beneficiaries assigned to the ACO. If an ACO's spending is below a minimum savings rate (MSR), the ACO is eligible for shared savings. For example, if an ACO has an MSR of 1.0%, spending below 99% of the benchmark will permit the ACO to share in savings (subject to quality performance).¹⁵

Next Generation ACOs

The Next Generation ACO model is similar to the MSSP, but provides participants with greater potential for shared savings and losses. Benchmarks are calculated using historic and regional Medicare Parts A and B expenditures. Thus, ACOs are responsible for total Parts A and B expenditures for beneficiaries assigned to the ACO over the course of the year, including spending for Part B drugs.

Next Generation ACOs may elect one of four payment mechanisms, as opposed to simply receiving FFS payments. Under a capitation-like payment called All-Inclusive Population-Based Payments (AIPBP), the ACO is responsible for paying claims to participant providers covered by the AIPBP agreement. Thus, CMMI allows the ACO to determine the payment rates which means that payment can differ from Medicare's established FFS payment rate.¹⁶

12 The Comprehensive ESRD Care Initiative. CMS. Available at: <https://innovation.cms.gov/files/slides/comprehensive-esrd-care-odf.pdf>.

13 Appendix B: LDO Financial Methodology (LDO-CEC Model). CMS. Available at: <https://innovation.cms.gov/Files/x/cec-financial-ldo.pdf>.

14 Comprehensive ESRD Care Model. CMS. Available at: <https://innovation.cms.gov/initiatives/comprehensive-esrd-care/>.

15 Shared Savings Program. CMS. Available at: <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/index.html>.

16 Next Generation ACO Model. CMS. Available at: <https://innovation.cms.gov/initiatives/Next-Generation-ACO-Model/>.

Pioneer ACOs

Pioneer ACOs also are responsible for total Medicare Parts A and B expenditures for beneficiaries assigned to the ACO, including Part B drugs. Similar to the Next Generation model, Pioneers may choose alternative payment mechanisms. These payment mechanisms do not change the benchmark, but rather, determine the type of risk facing the ACO and how CMS will pay for services provided by the ACO. For example, a Pioneer ACO may choose Alternative 1, which puts the ACO at full risk for all Part B revenue and shared risk for Part A revenue.¹⁷

Table: CMMI Programs and Part B Implications

Program Name	Year Announced	Aim	Scope	Relationship to Part B Drug Payment
Episode Payment Models (EPMs)				
Bundled Payment for Care Improvement (BPCI) Initiative ¹⁸	2011	Test episode-based payments	<ul style="list-style-type: none"> • Voluntary • Includes over 1,300 providers bearing risk • Includes up to 48 clinical conditions, selected by participants 	Providers (e.g., hospitals, physicians, PAC) bear risk for Medicare Parts A and B expenditures over defined episode time period
Comprehensive Care for Joint Replacement (CJR) Model ¹⁹	2015	Test a bundled payment for hip and knee replacements	<ul style="list-style-type: none"> • Mandatory • Covers 67 MSAs • 791 acute care hospitals are located in MSAs selected to participate in CJR²⁰ 	Hospitals bear risk for Medicare Parts A and B expenditures over defined episode time period
Oncology Care Model (OCM) ²¹	2015	Test episode-based payments to reduce the total cost of chemotherapy treatment	<ul style="list-style-type: none"> • Voluntary • 196 oncology practices • Expected to cover 175,000 cancer care episodes over the duration of the model²² 	Program incentivizes practices to reduce Medicare Part B expenditures, both for the initial chemotherapy application and across the six-month OCM episodes
Disease Specific Model				
Comprehensive ESRD Care (CEC) Model ²³	2013	Test new payment model for improving care for beneficiaries with ESRD	<ul style="list-style-type: none"> • Voluntary • 13 current ESRD Seamless Care Organizations (ESCOs) spanning 11 states • New application period ended July 15, 2016 	ESRD Care Organizations are at risk for total Medicare Parts A and B spending, including Part B drugs
Accountable Care Organizations (ACOs)				
Medicare Shared Savings Program (MSSP) ACOs ²⁴	2011	Test ACOs in the Medicare program for the first time	<ul style="list-style-type: none"> • Nationwide program – not a demonstration; ACOs must be assigned over 5,000 beneficiaries • 433 Shared Savings Program ACOs • 7.7 million assigned beneficiaries in 49 states plus Washington, DC²⁵ 	ACOs at risk for total Medicare Parts A and B expenditures, including Part B drugs

17 Pioneer ACO Model. CMS. Available at: <https://innovation.cms.gov/initiatives/Pioneer-aco-model/>.

18 Bundled Payments for Care Improvement (BPCI) Initiative. CMS. Available at: <https://innovation.cms.gov/initiatives/bundled-payments/>.

19 Comprehensive Care for Joint Replacement Model. CMS. Available at: <https://innovation.cms.gov/initiatives/CJR>.

20 Comprehensive Care for Joint Replacement Model Hospital List. CMS. Updated as of August 1, 2016. Available at: <https://innovation.cms.gov/Files/x/cjr-hospitals.xlsx>.

21 Oncology Care Model. CMS. Available at: <https://innovation.cms.gov/initiatives/oncology-care/>.

22 Oncology Care Model (OCM) Request for Applications (RFA). February 2015. Available at: <https://innovation.cms.gov/Files/x/ocmrf.pdf>.

23 Comprehensive ESRD Care Model. CMS. Available at: <https://innovation.cms.gov/initiatives/comprehensive-esrd-care/>.

24 Shared Savings Program. CMS. Available at: <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/index.html>.

25 Fast Facts: All Medicare Shared Savings Program (Shared Savings Program) ACOs. CMS. April 2016. Available at: <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/Downloads/All-Starts-MSSP-ACO.pdf>.



Next Generation ACOs ²⁶	2015	Test beneficiary and program enhancements under the ACO model (e.g., SNF 3-day waiver)	<ul style="list-style-type: none"> • 18 Next Generation ACOs participating • Minimum assignment of 10,000 beneficiaries (7,500 for rural ACOs) • Prospective assignment and voluntary attestation • Covers 1.0 million beneficiaries²⁷ 	ACOs at risk for total Medicare Parts A and B expenditures, including Part B drugs. An ACO may choose a payment option that allows the ACO to pay claims (and determine payment rates) to its own providers, rather than Medicare.
Pioneer ACO Model ²⁸	2011	Test the ACO model among providers experienced in care coordination; greater savings and losses and flexibility than MSSP	<ul style="list-style-type: none"> • Nine Pioneer ACOs participating in 2016. • Minimum assignment of 15,000 beneficiaries (5,000 for rural ACOs) • Prospective assignment and voluntary attestation • Covers 0.3 million beneficiaries²⁹ 	ACOs at risk for total Medicare Parts A and B expenditures, including Part B drugs

Conclusion

CMS has leveraged authorities granted to the agency by the Affordable Care Act to launch seven demonstrations that hold providers accountable for Part B spending, including expenditures for Part B drugs. Although CMS did not design the programs covered in this brief specifically to address Part B drugs, providers participating in these programs may modify their Part B prescribing, utilization, and treatment patterns in an effort to ensure that expenditures for all included Medicare services fall under the applicable spending benchmark. CMMI is required to evaluate all of its programs to assess their impact on the cost and quality of care for Medicare beneficiaries. Evaluation of these initiatives will provide critical insight for policymakers as they continue to explore strategies to control health care spending and improve value for Medicare services, including Part B drugs.

²⁶ Next Generation ACO Model. CMS. Available at: <https://innovation.cms.gov/initiatives/Next-Generation-ACO-Model/>.

²⁷ Subtracted total MSSP and Pioneer covered lives from the total ACO covered lives included in the January 2016 HHS press release. The resulting value is slightly higher as HHS included the 13 ESRD ACOs in the total for ACO covered lives.

²⁸ Pioneer ACO Model. CMS. Available at: <https://innovation.cms.gov/initiatives/Pioneer-aco-model/>.

²⁹ Sum of the total aligned beneficiaries listed in the Pioneer third performance year results for the nine ACOs that remain in the demonstration. Notably, the third performance year concluded in 2014.

