Medicare and Medicaid Reimbursement Issues for New Emerging Technologies: Spotlight on CAR-T and Other Cell and Gene Therapies

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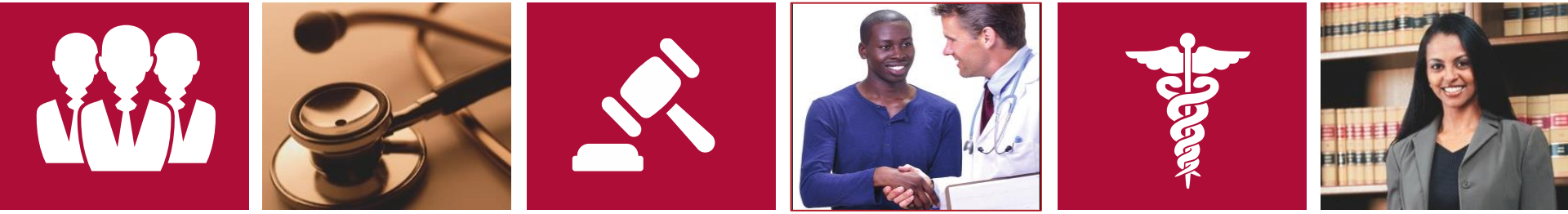

Agenda

- Drug Pricing Issues for Providers (R. Margulies)
- Case Study for CAR-T (J. Shah)
- Solutions to High Cost Therapies: Advancing Value-Based Payment (M. Hamilton Lopez)

PSA: Read our written materials!

Learning Objectives

- In 30 **exhilarating** minutes, you will learn:
  - How Medicare Parts A and B attempt to recognize the costs of transformative therapies in the hospital setting
  - How state Medicaid programs are pursuing new strategies to account for the new wave of cell and gene therapies
  - What programs/policies do exist to recognize transformative therapies, and what are their limitations

Medicare Part A Provider Reimbursement: Overview

- The inpatient payment rate is **all-inclusive**, meaning that drugs and biologics are not paid for separately.

- Hospitals are paid a **predetermined, prospective amount per discharge for all inpatient hospital admissions**. Discharges are classified by a patient's diagnoses and procedures into different groups, referred to as diagnosis-related groups (DRGs)**.**

Medicare Part A Provider Reimbursement: Overview (cont.)

- CMS determines the calculated cost of each MS-DRG case by **applying the hospital's overall cost-to-charge ratio (CCR), which is determined from the facility's most recent cost report to the individual patient's covered billed charges** which is then compared to the MS-DRG payment plus a fixed outlier threshold.

- Each DRG is assigned a weighting factor that indicates its relative cost as compared with all other DRGs. This weighting is used to calculate the payment rate for that DRG.
  - The methodology uses hospital inpatient claims from two years prior to the Federal fiscal year (e.g., 2017 claims are used for 2019 payment rates).

Medicare Part A: When is a Beneficiary an Inpatient?

- Typically, a beneficiary is an inpatient when they are formally admitted to a hospital with a doctor's order. The day before they are discharged is their last inpatient day.

- But note:
  - **3-Day Payment Window**
    - Hospital must include on the claim for an inpatient stay all outpatient diagnostic services and all admission-related outpatient nondiagnostic services that are furnished to a beneficiary in the 3-day window preceding their admission
  - **Two-Midnight Rule**
    - Providers should admit patients for inpatient admission when the patient is expected to stay in the hospital for at least two midnights

Medicare Part A: Provider Payment for Drugs

- The use of a particular drug or device does not generally change the inpatient payment rate for a given type of case, except to the extent costs impact historical cost reports (which in turn can impact/adjust DRG payment rates).

- Typically, it takes three years for the charges associated with a new technology to be reflected in the DRG weighting factor to which that technology is assigned.

Medicare Part A: Outlier Payments

- **Outlier payments** are additional payments made to hospitals when the costs of treating a particular patient are extraordinarily high, as compared with the costs of care for other cases assigned to the same DRG
- Outlier payments are calculated by taking 80% of the difference between the covered charges of a case and the outlier threshold. The outlier threshold is composed of the DRG payment plus a fixed amount
  - The fixed amount in 2019 is $25,769. In other words, if the costs of care exceed the payment rate by $25,769, then an additional outlier payment is payable.
- Important note: MS-DRGs must be **budget-neutral**; extreme high costs via outlier payments can divert dollars from other, more common cases to high-cost cases

Medicare Part A: New Technology Add-on Payment

- Congress created New Technology Add-on Payment (NTAP) to address concerns about adoption of innovation given the inpatient prospective payment system.

- To qualify, the new technology must:

  - **"Substantially improve"** health outcomes for Medicare beneficiaries relative to technologies previously available.

  - Be **"new"** (costs not captured in the claims data)

  - Have **costs** that are not insignificant /DRG inadequately reflects the cost of the new technology

Medicare Part A: New Technology Add-on Payment (cont.)

Year	Applied	Approved	Withdrawn	Denied Due to Not Meeting the Following Criteria			
				FDA Approval	Newness	Cost Threshold	Substantial Clinical Improvement
FY 2003	4	1	1		2	1	
FY 2004	3	1			1	1	
FY 2005	10	2			5		3
FY 2006	8	2		1	2		3
FY 2007	3	1	1				1
FY 2008	1						1
FY 2009	4	1		3			
FY 2010	6	1	4				1
FY 2011	3	1	2				2
FY 2012	3		1		1		1
FY 2013	4	3		1			
FY 2014	5	3	1	2			
FY 2015	7	3	2		1		2
FY 2016	9	2	2	1	2		2
FY 2017	9	5	2		2		1
FY 2018	9	3	5	1			
FY 2019	15	7	7	1			
Total	**93**	**36 (39%)**	**28 (30%)**	**10**	**16**	**2**	**17**

Medicare Part A: NTAP Limitations

- By regulation, NTAP payments may not exceed the lessor of 50% of the cost of the new technology or 50% of the amount that the calculated cost of the inpatient case exceeds the MS-DRG payment
- Add-on payment availability is determined on a **patient by patient** basis, and maximum NTAP may not be paid for each individual case
- NTAP available for only **2-3 years** from date product first available on the market
- Hospitals do not know at time of treatment whether case qualifies for an add-on payment

Medicare Part B Provider Reimbursement: Overview

- Unlike in the inpatient setting, most drugs and biologicals paid separately at ASP+6%

- Outpatient payment is paid on the basis of the **ambulatory payment classification** (APC) coding system.
  - Each APC is composed of many component procedures that are identified with either a CPT code or a HCPCS code.
  - Like DRGs, procedures generally are grouped into APCs such that they resemble each other clinically and in terms of resource use.

- Outpatient payments rates are published annually in the Outpatient Prospective Payment System (OPPS) rulemaking.

Medicare Part B: Provider Payment for Drugs

- First ask: is it **Part B** or **Part D**?

- A drug is covered under Part B if it falls into any of these three categories:
  - Prescribed and dispensed **incident to** a physician's services and not usually self-administered (E.g., chemotherapy drugs)
  - Specifically **named in the Part B statute** (E.g., EPO, Intravenous Immunoglobulin (IVIG), oral anti-emetics).
  - Necessary for the effective use of **durable medical equipment** (E.g., drugs administered through external infusion pumps)

Medicare Part B: Provider Payment for Drugs (cont.)

- Some drugs and biologicals are **packaged** into the payment for the service or procedure, while others may be **separately paid**

- Packaged:
  - CMS, in its discretion, packages low-cost drugs (in 2019, $125) into the corresponding APC

- Separately payable drugs:
  - **Unlike IPPS**, in which virtually all drugs are bundled into the corresponding DRG, in OPPS, **most drugs are paid separately**, outside of the corresponding APC

Medicare Part B: Provider Payment for Drugs (cont.)

- Payment for separately payable drugs under all of Part B (including OPPS) is based on Average Sales Price (ASP) Methodology, which includes Wholesale Acquisition Cost (WAC)
  - The payment rate in 2019 for separately payable drugs in the hospital outpatient setting is **ASP plus 6%**:
    - Because of sequestration enacted in 2012, the actual add-on is 4.3%.
  - Except for payment for drugs acquired under the 340B program:
    - CMS announced a policy change applicable for CY 2018 for drugs acquired via the 340B program and paid under the OPPS to 340B hospitals are paid at ASP – 22.5%

Medicare Part B: Transitional Pass-through Payment

- CMS makes additional payments to hospitals for new drugs and biologicals whose costs are "not insignificant" in relation to the OPPS payment for the procedures or services associated with the new drug, device, or biological

- Under the statute, these transitional pass-through payments can be made for a period of **at least two years, but not more than three years**, after payment was first made for the product as a hospital outpatient service under Medicare Part B
  - The payment rate under pass-through is currently set at ASP+6% (minus the portion of the APC that CMS determines is associated with the drug)
  - As a new drug is approved for pass-through status, it receives a temporary product-specific HCPCS code (C-code)
  - **Note**: pass-through drugs are exempt from the new 340B hospital payment cuts

Medicaid Drug Reimbursement: Overview

- State Medicaid program payment for hospital items and services varies from state to state (and whether or not payment is made on a fee-for-service basis, or via a state-contracted managed care organization), and depending on whether the items are provided in the inpatient or outpatient setting

- Drug payment depends on whether or not the drug meets the definition of a "covered outpatient drug"
  - **Importantly** a covered outpatient drug does not include a drug bundled into a hospital payment rate
  - Medicaid programs do pay outlier payments, but they tend to be less generous than Medicare
  - There is no NTAP in Medicaid

Medicaid Drug Reimbursement: Outpatient Drugs

- Under Section 1927 of the Social Security Act, a manufacturer typically must enter into an agreement under which a manufacturer agrees to pay rebates to states in exchange for the state guaranteeing coverage of the manufacturer's "covered outpatient drugs."
  - In exchange for the manufacturer entering into a rebate agreement, a state "may exclude or otherwise restrict coverage" of a covered outpatient drug under only limited circumstances.
  - Rebate amounts include a base rebate (23.1% of AMP), an inflationary penalty, and any optional supplemental rebates

Medicaid Coverage of High-Cost Drugs

- Historically, state Medicaid programs have sought to include the cost of drugs in the bundled payments made to hospitals, meaning that hospitals are not separately reimbursed for drugs they provide to their patients

- However, several states have recently experimented with payment systems that do attempt to recognize the new high-cost therapies
  - New York (carve-out model)
  - Massachusetts (carve-out model)
  - Oklahoma, Michigan and Colorado (VBP arrangements)

Conclusion

- Medicare and Medicaid have limited flexibility to recognize the cost of transformative therapies

- As the number of transformative and/or curative therapies grows, reforms to existing payment systems should be considered in order to better capture the promise of these new therapies

Thank You

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