CLINICAL PATHWAYS AND POLICY TO GUARD AGAINST MISALIGNED INCENTIVES

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The application of clinical pathways and their enforcement through quality metric benchmark setting and appropriate use criteria is needed to guard against perverse financial incentives that encourage overutilization and underutilization. Moving forward, the more diligent payers and integrated delivery networks can be in evaluating and incorporating utilization criteria when establishing clinical pathways, the better off our system will be.

Due to current market dynamics and existing policies, payers and at-risk providers have their own financial incentives that may be contrary to that of society, as well as patients, in terms of clinical outcomes. Clinical pathways are typically built to guide clinicians to prescribe the most appropriate treatment to optimize clinical and financial outcomes.[1-3] However, clinical pathways can also be used to ensure provider and payer incentives are aligned and reinforce what is best for patients and members via the lens of population health.

This article will explore different payer policies and market dynamics that can result in the overutilization or underutilization of healthcare treatments (Table 1). It also explores opportunities to mitigate the unintended consequences of previous policies, both through new Centers for Medicare & Medicaid Services (CMS) policy efforts and clinical pathway application. Because most spending in healthcare is funded by the government, CMS policies determine how most of healthcare funding is spent.

Underutilization

Underutilization of care services and treatments can occur when there are incentives that reward the reduction of costs in the short term. This is problematic when such choices result in poorer, long-term patient outcomes. Such underutilization is caused by some variation of capitation, whereby providers and third-party payers (like Medicare Advantage [MA] plans) are given a fixed budget to treat a patient. The fixed budget creates an incentive to limit the costs associated with diagnosis and treatment. This issue can be exacerbated by the fact that many patients may be reluctant to pursue additional care; if patients perceive a lack of attention to follow-up care, this care may be lost.

Table 1: Healthcare Market Dynamics of Incentive-Driven Service Utilization

Policies Contributing to Underutilization	Policies Contributing to Overutilization	Policies Contributing to Balanced Utilization
Capitated payments	Fee-for-service reimbursement	New technology add-on payment
Bundled payments	Buy-and-bill medication reimbursement	Quality measures/5-star rating
Total cost-of-care fixed benchmarking		Clinical decision support mechanisms

MA plans receive an annual capitated payment from Medicare for each enrollee depending on each individual's risk profile. Capitated payments to both providers and MA plans view cost over a 1-year time horizon and encourage providers and payers to decrease utilization of high-cost diagnostics and treatments. Additionally, benchmark targets for MA plans do not account for new therapies. MA benchmark levels in each county are based on the practice patterns of physicians and other providers who bill fee-for-service (FFS) Medicare over a 5-year period. Innovative therapies that modify the standard of care in a treatment setting are not included in previous costs. Low benchmarks that fail to account for new medical innovations push MA plans to restrict the use of innovative products.

Medicare regulations like the 14-day rule also affect utilization of molecular tests and diagnostics. The 14-day rule requires that molecular tests using blood or tissue samples of inpatient origin must be paid for by the hospital from its diagnosis-related group (DRG) reimbursement while the patient is an inpatient and for up to 14 days after discharge or 30 days after the biopsy, whichever comes first. Similar to capitation, the 14-day rule incentivizes decreasing the cost of diagnostics but has the unintended consequence of underutilizing tests that are necessary for determining the best treatment course for a patient or encouraging the use of lower-cost, nonstandardized tests developed by hospitals. For example, a patient with newly diagnosed stage IV non-small cell lung cancer (NSCLC) who is diagnosed in the hospital setting may be biopsied in the hospital as part of receiving that diagnosis. National Comprehensive Cancer Network guidelines base NSCLC treatment recommendations on driver mutations that can be tested for in the hospital setting with a biopsy. Driver mutations like EGFR, ALK, and KRAS can help determine whether a patient should receive a targeted tyrosine kinase inhibitor or if they are eligible for a clinical trial. Many Food and Drug Administration (FDA)-approved therapies have a standardized companion diagnostic that tests blood or tissue samples for these specific mutations. However, hospitals may use a lower-cost, nonstandardized, laboratory-developed test rather than a companion diagnostic or even forgo testing for the patient, resulting in a delay in obtaining the best treatment for that patient.

Recent changes to the Medicare 14-day rule allow outpatient providers to order these companion diagnostics, but the provider must wait for the patient to be outpatient before ordering the test. Additionally, the patient must have the diagnostic completed outside of the hospital setting, which can further delay proper treatment since the patient may first need to wait to be seen by the outpatient provider. Even worse, this rule may result in the patient starting the wrong treatment in an effort to get the patient started on any treatment. Further changes to this rule may be needed to address this issue.[4]

Overutilization

As the healthcare system and CMS policies move away from volume- to value-based reimbursement, overutilization is becoming less of an issue, but there are several older policies that are still in effect. FFS still dominates as a revenue source for providers and increases the utilization of diagnostics and medical services. The FFS model simply pays for services rendered, which leaves it vulnerable to misuse and overutilization with no incentive to consider cost. Neither the patient nor the provider "feels" the cost of the service at the time it is prescribed, so it promotes overuse of medical services and high levels of spending.

FFS also drives overutilization as an unintended consequence of lower Medicare reimbursement rates compared with commercial plans, driving a need for providers to produce more income by increasing their volume of services. This scenario creates a conflict of interest for providers, even tempting them to order unnecessary tests and procedures. Moreover, FFS encourages a fragmented health care system where care is not coordinated and may result in repeated tests.

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Buy-and-bill allows providers to collect a proportion of drug costs, which incentivizes the use of higher-cost treatments. Buy-and-bill refers to practices purchasing these drugs and then billing insurers when the drugs are used to treat specific patients. Reimbursement for buy-and-bill drugs is a large source of revenue for many practices, especially in oncology, where it creates an incentive for outpatient oncology practices to use more expensive therapies rather than pursuing more cost-effective treatment strategies. New CMS rules have mitigated this incentive in a subset of enrollees by allowing MA plans to manage Part B drugs through step therapy.[5]

Buy-and-bill also has the unintended consequence of placing upward pressure on the launch prices of new provider-administered drugs, which are reimbursed by Medicare based on average sales price (ASP). The ASP is calculated using quarterly drug pricing data submitted to the CMS by drug manufacturers, but there is a 6-month lag before sales are reflected in the ASP. This lag limits price increases for Part B drugs, since they can result in reimbursement being less than the cost of procuring the drug. This can push manufacturers to maximize their launch prices because they know their ability to increase price later will be limited.

Realigning Incentives

The new technology add-on payment (NTAP) is used by Medicare to reimburse hospitals for infusing new therapies that show evidence of clinical improvement from previous therapies and that are inadequately paid for under current DRG payments. NTAP does not require novel drugs and devices to be used for their FDA-approved indication.[6] This is an attempt to prevent underutilization of therapies that are not accounted for in the DRG, while the prospective payment system recalibrates to reflect the cost of the new technology.

Quality measures are another mechanism used by Medicare to make sure diagnostics and medications are appropriately utilized, even though plans have traditionally been reimbursed by Medicare through a capitated rate based on patient risk profile. MA star ratings are based on more than 40 quality measures that ensure plans are providing adequate preventive screenings and vaccines, management of chronic conditions, enrollee satisfaction, and timely appeals.[7] Enrollees can see star ratings when choosing a plan, and most enrollees choose plans with at least 4 stars. Additionally, the Affordable Care Act created quality bonus payments for MA plans that achieve at least 4 stars in order to incentivize these plans to use tests and treatments appropriately.

Another way to align incentives that uses clinical pathways directly is via clinical decision support mechanisms (CDSMs). Beginning in 2020, advanced diagnostic imaging services under Medicare Part B will be judged as appropriate based on appropriate use criteria that are derived from established CDSMs, which often use a form of clinical pathways.[8,9] Failure to follow these clinical pathways, which could result in overutilization by providers that have a financial stake in these diagnostic tests, would see CMS roll back funds as a means of enforcing best clinical practice application.

Conclusion

Clinical pathways and policy changes have a role to play in ensuring appropriate utilization of treatments and diagnostics to optimize clinical and financial outcomes for patients and payers. Beyond policy changes, clinical pathways can be applied to CDSMs and benchmark setting for populations, which can then be set as quality metric benchmarks to ensure appropriate utilization. The application of clinical pathways and their enforcement through quality metric benchmark setting and appropriate use criteria is needed to guard against perverse financial incentives that encourage overutilization and underutilization. Moving forward, the more diligent payers and integrated delivery networks can be in evaluating and incorporating utilization criteria when establishing clinical pathways, the better off our system will be.

REFERENCES

1. Wong W. The evolution of clinical pathways in oncology. *J Clin Pathways.* 2015;1(1):37-42.
2. Gesme DH, Wiseman M. Strategic Use of Clinical Pathways. *J Oncol Pract.* 2010;7(1):54-56. doi:10.1200/JOP.2010.000193
3. Zon RT, Edge SB, Page RD, et al. American Society of Clinical Oncology criteria for high-quality clinical pathways in oncology. *J Clin Pathways.* 2017; 13(3):207-210.
4. Centers for Medicare & Medicaid Service (CMS). Laboratory date of service policy. cms.gov website. https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Clinical-Lab-DOS-Policy. Updated June 28, 2019. Accessed February 2, 2020.
5. Centers for Medicare & Medicaid Service (CMS). Medicare advantage and part D drug pricing final rule (CMS-4180-F) [fact sheet]. cms.gov website. https://www.cms.gov/newsroom/fact-sheets/medicare-advantage-and-part-d-drug-pricingfinal- rule-cms-4180-f. Published May 16, 2019.
6. Moorman A, Gooding M, Coffelt J. How a new technology add-on payment (NTAP) works. avalere.com website. https://avalere.com/insights/how-a-new-technologyadd- on-payment-works. Published August 14, 2019. Accessed February 2, 2020.
7. Centers for Medicare & Medicaid Service (CMS). Fact sheet – 2020 part C and D star ratings. https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/Downloads/2020-Star-Ratings-Fact-Sheet-.pdf. Accessed February 2, 2020.
8. Centers for Medicare & Medicaid Service (CMS). Appropriate use criteria program. cms.gov website. https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Appropriate-Use-Criteria-Program/index. Updated January 10, 2020. Accessed February 2, 2020.

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