REPORT 03 OF THE COUNCIL ON MEDICAL SERVICE (A-23)
Private Insurer Payment Integrity
(Reference Committee A)

EXECUTIVE SUMMARY

At the 2022 Annual Meeting, the House of Delegates referred Resolution 110-A-22, which asked the American Medical Association to advocate for private insurers to require, at a minimum, to pay for diagnosis and treatment options that are covered by government payers such as Medicare and seek legislation or regulation to ensure that private insurers shall not be allowed to deny payment for treatment options as "experimental and/or investigational" when they are covered under government plans.

Private insurers may each make their own medical coverage determinations, which can vary across their product lines. Private insurers sometimes are able to deny coverage by labelling a diagnostic or treatment "investigational," "experimental," or "not medically necessary," which may be exacerbated by the burdensome appeals process required to request reconsideration of a denial or adverse determination.

Of government payers, Medicare is typically considered the national benchmark, particularly since it is a federal defined benefit program, with decisions centralized within the Centers for Medicare & Medicaid Services. Medicare develops National Coverage Determinations (NCDs) that are applied for all Medicare beneficiaries meeting the coverage criteria. The NCD process is a transparent, nine-month, evidence-based process with opportunities for public comment and supplemental technological assessment, which may include clinical studies. The supposition that private insurers' medical coverage determinations are more restrictive than Medicare's is not necessarily true and may be based on the perception that traditional Medicare fee-for-service coverage is more robust due to its paucity of prior authorization requirements.

While the Patient Protection and Affordable Care Act (ACA) establishes benefit mandates in the form of essential health benefits (EHB), private ACA marketplace insurers have demonstrated hesitancy in fully embracing the ACA EHB benefit mandate, even as it continues to be challenged by decisions such as *Braidwood Management Inc. et al. v. Becerra et al*.

While maintaining a commitment to minimizing benefit mandates is essential, there is clearly a need for transparency of coverage determinations, specifically regarding disparities across insurer product lines. The NCD process is very robust and might serve as a template for establishing a comprehensive, evidence-based process to allow for consistency in determinations of experimental/investigational status and transparency in coverage determinations from which insurers can develop benefit packages. Use of such a process would eliminate seemingly arbitrary decisions by private insurers to deem a diagnosis and treatment option as "experimental/investigational" in order not to have to pay for it.

REPORT OF THE COUNCIL ON MEDICAL SERVICE

CMS Report 3-A-23

Subject: Private Insurer Payment Integrity (Resolution 110-A-22)

Presented by: Lynn Jeffers, MD, MBA, Chair

Referred to: Reference Committee A

At the June 2022 Annual Meeting, the House of Delegates referred Resolution 110, which was sponsored by the New York Delegation. Resolution 110-A-22 asked the American Medical Association (AMA) to advocate for private insurers to require, at a minimum, to pay for diagnosis and treatment options that are covered by government payers such as Medicare and seek legislation or regulation to ensure that private insurers shall not be allowed to deny payment for treatment options as "experimental and/or investigational" when they are covered under government plans. Testimony at the June 2022 Annual Meeting regarding the resolution was generally opposed, highlighting the complex issues surrounding private insurer versus governmental coverage, specifically regarding benefit mandates and the differential drivers utilized in making medical coverage determinations. This report focuses on the need for transparency of medical coverage determinations, studies how 'investigational' diagnosis and treatment options are determined, highlights essential AMA policy, and presents new policy recommendations.

BACKGROUND

Coverage Determinations by Private Insurers

Private insurers are a fragmented group of commercial plans operating under a broad range of federal regulations as well as insurance and coverage rules and regulations that vary by state. Some private insurers operate nationally. While they may look to governmental precedent in certain situations, they each make their own medical coverage determinations, which can vary across their product lines. Access to private insurers' medical coverage decisions is limited, but not entirely restricted. For example, on the UnitedHealthcare (UHC) web site, the UHC commercial policy on coverage of "Off-Label/Unproven Specialty Drug Treatment" includes a Food & Drug Administration (FDA) section, noting that it is "to be used for informational purposes only…FDA approval alone is not a basis for coverage."

Private insurers sometimes are able to deny coverage by labelling a diagnostic or treatment "investigational," "experimental," or "not medically necessary," which may be exacerbated by the burdensome appeals process required to request reconsideration of a denial or adverse determination. Patients are typically not aware of their right to appeal or legal due process protections. This health insurance illiteracy is compounded among patients with limited access to technology and other resources, leading to the potential for substantial health inequities across private plans.

Coverage Determinations by the Centers for Medicare & Medicaid Services

Of government payers, Medicare is typically considered the national benchmark, particularly since it is a federal defined benefit program, with decisions centralized within the Centers for Medicare & Medicaid Services (CMS). Title XVIII of the Social Security Act established Medicare with coverage that is limited to items and services that are:

- reasonable and necessary for the diagnosis or treatment of an illness or injury; and
- within the scope of a Medicare defined benefit category.

National Coverage Determinations

The vast majority of Medicare coverage is determined on the local level by clinician contractors (Medicare Administrative Contractors [MACs] making Local Coverage Determinations [LCDs]). However, in some cases, Medicare develops National Coverage Determinations (NCDs) that are applied for all Medicare beneficiaries meeting the coverage criteria.

The NCD process is a nine-month, evidence-based process with opportunities for public comment and supplemental technological assessment by the Medicare Evidence Development & Coverage Advisory Committee (MEDCAC), which may include clinical studies. If the NCD determines coverage of an item or service only in the context of clinical study, it falls under the Coverage with Evidence Development (CED) program. NCDs in the CED program use available evidence to fit that item or service within that benefit category. As such, CMS can act as a coverage gatekeeper via the NCD process. This mechanism has been used over the past few decades and includes evidence-based guidelines for coverage.

Since it has been nearly eight years since the criteria for CED were last evaluated, MEDCAC is currently re-examining the requirements for clinical studies submitted for CMS coverage under CED, acknowledging that the update is needed since technologies have become more complex. MEDCAC also has conveyed "a commitment to greater transparency in decision-making, to making certain that study methodologies are 'fit to purpose' as determined by the topic, questions asked, health outcomes studied, and to making certain that the populations studied are representative of the diversity in the Medicare beneficiary population."[1]

The NCD process has been amended on several occasions (e.g., The Medicare Prescription Drug, Improvement, and Modernization Act of 2003), with updates made to the process for opening, deciding, or reconsidering NCDs under the Social Security Act. The 2013 update developed an expedited administrative process utilizing specific criteria to remove certain NCDs older than ten years, thereby enabling MACs to determine coverage under the Social Security Act for sunset NCDs. For 2023, CMS has updated Medicare coverage policies for colorectal cancer screening in order to align with recent United States Preventive Services Task Force (USPSTF) and national medical specialty society recommendations.[2]

Transparency is a keystone to the process, as CMS issues an annual report listing the NCDs made in the previous calendar year in the form of a report to Congress. Additionally, there is an NCD dashboard, outlining the status of NCDs at each stage of the process (i.e., under review, reviewed but not yet opened, opened and undergoing national coverage analysis, and finalized). CMS houses all Medicare coverage determinations in the Medicare Coverage Database (MCD). The MCD includes LCDs as well as NCDs, along with reports on each.

The supposition that private insurers' medical coverage determinations are more restrictive than Medicare's may be based on the perception that traditional Medicare fee-for-service coverage is more robust due to its paucity of prior authorization requirements. Data indicates otherwise, such as with NCDs for medical devices. For each of the 47 medical devices considered for NCDs between February 1999 and August 2013, it was found that NCDs were equivalent to the corresponding private insurer policies roughly half of the time, more restrictive approximately a quarter of the time, and less restrictive about a quarter of the time.[3]

Food and Drug Administration

The notion that Medicare "adopts" diagnostic and treatment options once approved by the FDA is similarly problematic. Medicare does not automatically cover all FDA-approved devices and drugs. Between 1999 and 2011, Medicare covered FDA-approved drugs or devices only 80 percent of the time.[4] Additionally, Medicare has been found to have more stringent requirements than the FDA, particularly for drugs or devices in patients with comorbidities.

The Medicare Benefit Policy Manual (Chapter 14 – Medical Devices) outlines that Medicare will cover FDA-approved and Institutional Review Board (IRB)-approved investigational devices "provided the investigational device meets certain requirements, including: (1) The device or services associated with the use of a device are provided to the beneficiary within the start and end dates contained in the master file; (2) There are no regulations, national coverage policies, or manual instructions that would otherwise prohibit Medicare coverage."

Medicare Investigational Device Exemption

While Medicare normally does not cover experimental or investigational procedures, it does offer an exemption for investigational devices to allow for coverage under some circumstances. The Medicare Investigational Device Exemption (IDE) was developed as part of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) and includes two categories:

- Category A (Experimental): An innovative/experimental device for which "absolute risk" of the device type has not been established (i.e., initial questions of safety and effectiveness have not been resolved and the FDA is unsure whether the device type can be safe and effective). There is no Medicare coverage for a Category A device but Medicare covers routine care items and services in the trial. An example is the CG-100 Intraluminal ByPass Device.
- Category B (Non-experimental/non-investigational): A device for which the underlying questions of safety and effectiveness of that device type have been resolved. Medicare allows for coverage of the Category B device as well as for routine care items and services in the trial. An example is the Viper Catheter System.

In 2015, CMS shifted responsibility for review and approval of IDE studies from the MACs to a centralized CMS process, which includes a publicly accessible, updated list of Approved IDE Studies.

Medicare Coverage of Innovative Technology and Definition of Reasonable and Necessary

In January 2021, CMS released a final rule on The Medicare Coverage of Innovative Technology and Definition of "Reasonable and Necessary,"[5] which established pathways to payment for innovative technologies supported by high-quality, validated clinical data. The rule automatically

provided four years of coverage for all Medicare beneficiaries for newly approved medical devices, in order to accelerate availability of medical devices approved through the FDA breakthrough pathway for innovative technologies.

As part of the rule, CMS proposed automatically transferring the coverage policy of commercial insurance to Medicare beneficiaries for new products. In two identical comment letters (November 2020 and April 2021), the AMA outlined several concerns with the proposal, namely the potential loss of transparency in Medicare coverage decisions if tied to commercial health insurer policies beholden to shareholder expectations. The independent, public comment process utilized by CMS to make coverage decisions appropriate for the Medicare population would be replaced with coverage decisions based on objectives such as litigation avoidance or competitive advantage. The AMA argued that the focus should remain on what is most suitable and safest for Medicare beneficiaries based on Medicare's determination.

After considering these and other comments, CMS rescinded the rule in November 2021, citing concerns about lack of sufficient patient protections and lack of evidence of clinical benefit for the newly approved medical devices in the Medicare population. At the present time, CMS is working on a new proposed rule to create an accelerated Medicare coverage pathway, building on prior initiatives such as CED.[6]

AFFORDABLE CARE ACT BENEFIT MANDATES

The Patient Protection and Affordable Care Act (ACA) requires non-grandfathered health plans in the individual and small group markets to cover the following essential health benefits (EHB): (1) ambulatory patient services; (2) emergency services; (3) hospitalization; (4) maternity and newborn care; (5) mental health and substance use disorder services including behavioral health treatment; (6) prescription drugs; (7) rehabilitative and habilitative services and devices; (8) laboratory services; (9) preventive and wellness services and chronic disease management; and (10) pediatric services, including oral and vision care. The Department of Health and Human Services (HHS) regulations define EHB using state-specific benchmarks. Since 2020, states have been granted greater flexibility in establishing new standards for their EHB benchmark plans. Non-grandfathered health plans cannot refuse coverage or limit benefits for pre-existing conditions.

Since the passage of the ACA in 2010, there have been more than 2,000 state and federal actions attempting to limit, alter, or repeal it.[7] Most recently, in *Braidwood Management Inc. et al. v. Becerra et al.*, a federal judge ruled that insurers are no longer required to provide preventive services recommended by USPSTF at no cost. While some states have challenged parts or all of the ACA through legislation, others have acted to preserve the ACA by codifying certain provisions into state law.

Private ACA marketplace insurers have demonstrated hesitancy in fully embracing the ACA EHB benefit mandate, even as it continues to be challenged. For example, while insurers were initially required to cover preexposure prophylaxis (PrEP), a medication that prevents the transmission of human immunodeficiency virus in high-risk populations (e.g., gay and bisexual men of color) without cost sharing, not all insurers extended the benefit to the ancillary services (e.g., venipuncture, office visits) required to provide PrEP. HHS had to issue subsequent guidance to clarify that insurers were required to cover PrEP ancillary services under their EHBs. As decisions such as *Braidwood Management Inc. et al. v. Becerra et al.,* erode the ACA EHB benefit mandate, it will become increasingly important that private ACA marketplace insurers are held accountable for covering all current ACA EHB benefit mandates.

AMA POLICY

The AMA's longstanding goals to allow markets to determine benefit packages in order to permit a wide choice of coverage options and to refrain from jeopardizing coverage to currently insured populations are reflected in numerous AMA policies as well as in the AMA Proposal for Reform, which is grounded in AMA policies concerning pluralism, freedom of choice, freedom of practice, and universal access for patients. AMA policy supports the minimization of benefit mandates to allow markets to determine benefit packages, permitting a wide choice of coverage options.

Among the most relevant policies are those that:

- Oppose new health benefit mandates unrelated to patient protections (Policy H-185.964);
- Advocate for the minimization of benefit mandates (Policy H-165.856);
- Support maximization of patient choice (Policy H-165.839) and free market choice of plans (Policy H-330.912);
- Encourage payers to utilize transparent and accountable processes for developing and implementing coverage decisions and policies (Policy D-185.986);
- Assure reasonable payment levels for mandated benefits in health insurance policies (Policy D-385.966); and
- Call for the AMA to develop model legislation and/or regulations to require that commercial insurance companies, state Medicaid agencies, or other third party payers utilize transparent and accountable processes for developing and implementing coverage decisions and policies (Policy D-185.986).

While AMA policy opposes blanket benefit mandates, there is policy on coverage of specific conditions and services. For example, Policy H-185.967 supports that treatment of pediatric congenital or developmental deformities or disorders due to trauma or malignant disease should be covered by all insurers, Policy H-185.957 supports legislation that requires all third party payers that cover surgical benefits to cover all strabismus surgery where medically indicated, and Policy D-185.973 encourages insurance coverage of and payment for reconstructive services for the treatment of physical injury sustained from intimate partner violence. The AMA defended Policy D-185.979 by filing an amicus brief in *Braidwood Management Inc. et al. v. Becerra et al.*, which challenged support for first dollar coverage of preventive services.

The AMA definition of "medical necessity" (Policy H-320.953), urges payers to share third party methodologies for determining medical necessity, and advocates for the opportunity for treating physicians to provide medical evidence toward those determinations (Policy H-320.995). The AMA's definition of medical necessity is included in state model legislation and has been enacted in several states as a required definition, rather than allowing plans to develop their own definitions. Policies H-320.968 and H-320.982 support that denial of medical necessity of services or request for prior authorization be recommended by a physician of the same specialty as the treating physician.

Finally, there is AMA policy to protect patients and physicians and encourage innovation in the context of experimental or investigational treatments. Policy D-460.967 calls for the AMA to study the implementation of expanded access programs, accelerated approval mechanisms, and payment reform models to increase access to investigational therapies. Policy H-460.965 states that the AMA should pursue legislation and regulatory reform to mandate third party payer coverage of patient care costs of nationally approved scientifically based research protocols. Policy H-480.996 supports that regulations be promulgated or interpreted so as to not interfere with the

patient/physician relationship or impose regulatory burdens that may discourage creativity and innovation in advancing device technology.

DISCUSSION

While maintaining a commitment to minimizing benefit mandates is essential, there is clearly a need for transparency of coverage determinations, specifically regarding disparities across insurer product lines. An insurer may cover something considered preventive under one product line yet fail to cover the same thing under another product line. Such arbitrary coverage decisions not only question payer integrity but also introduce superfluous physician administrative burdens, such as prior authorization requirements.

While the AMA advocates for market-based solutions for coverage, there is presently a floor of benefits nationally as ACA plans must cover certain conditions. ACA coverage decisions for non-elective care at a basic level is necessary so that essential care is not determined by a patient's socioeconomic status. While it would be helpful for private and governmental insurers to be cognizant of each other's coverage decisions, it may not be ideal for them to be perfectly aligned given that Medicare is sometimes more restrictive and sometimes less restrictive. However, to encourage innovation, the process for gaining coverage must be transparent and expeditious. It would be beneficial to continue to expand the ability of CMS to proactively engage coverage of breakthrough therapies and devices at product launch – rather than having to wait for an NCD to be established. When CMS requires additional studies prior to coverage, this feedback should ideally be provided during the product development phase, not after the product is approved and available to the public, when finding patients to enroll in trials is more difficult.

The NCD process is very robust and might serve as a template for establishing a comprehensive, evidence-based process to allow for consistency in determinations of experimental/investigational status and transparency in coverage determinations from which insurers can develop benefit packages. The process could include online tools to allow physicians to easily check coverage status rather than requiring completion of a prior authorization form and waiting for a response. Implementation of such a process would not preclude private insurers from offering additional or alternative benefits that would distinguish their products in the marketplace, allowing for a wide choice of coverage options in keeping with AMA policy. In following established precedents, it may amend the base level for what is considered medically necessary care (e.g., USPSTF grade A or B recommendations are covered without cost-sharing under the ACA).

Use of such a process would eliminate seemingly arbitrary decisions by private insurers to deem a diagnosis and treatment option as "experimental/investigational" in order not to have to cover it. There is considerable variation in how "experimental/investigational" diagnosis and treatment options are determined, which only escalates concerns regarding subjective and inequitable decisions. While some insurers may define experimental/investigational services as an intervention that has not yet been determined to be medically effective for the condition being treated, others describe it as something that has undergone basic laboratory testing and received approval from the FDA to be tested in human subjects. The definition of experimental/investigational is a continuum rather than a standard as it is contingent upon discrete, independent evaluations that vary from insurer to insurer. While insurers may profess applying reasonable interpretation of their policy provisions, those are also variable and lacking a standard.

RECOMMENDATIONS

The Council on Medical Service recommends that the following be adopted in lieu of Resolution 110-A-22, and the remainder of the report be filed:

1. That our American Medical Association (AMA) support the development of a comprehensive, evidence-based process to establish consistency in determinations of experimental/investigational status and transparency in coverage determinations from which insurers can develop benefit packages. (New HOD Policy)

2. That our AMA support voluntary programs that expedite review for coverage by private and governmental insurers when requested by either the manufacturer or third parties such as national medical specialty societies. (New HOD Policy)

3. That our AMA amend Policy D-185.986 by the addition of one new clause, as follows: 4. Our AMA will advocate that when clinical coverage protocols are more restrictive than governmental payers, that private insurers and benefit managers should include the clinical rationale substantiating their coverage policies. (Modify Current HOD Policy)

4. That our AMA reaffirm Policy H-185.964, which opposes new health benefit mandates unrelated to patient protections.(Reaffirm HOD Policy)

5. That our AMA reaffirm Policy H-165.856, which advocates for the minimization of benefit mandates. (Reaffirm HOD Policy)

6. That our AMA reaffirm Policy H-320.995, which urges payers to share third party methodologies for determining "medical necessity," and advocates for the opportunity for treating physicians to provide medical evidence toward those determinations. (Reaffirm HOD Policy)

7. That our AMA reaffirm Policy D-460.967, which calls for study of the implementation of expanded access programs, accelerated approval mechanisms, and payment reform models to increase access to investigational therapies. (Reaffirm HOD Policy)

Fiscal Note: Less than $500.

REFERENCES

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