

American Osteopathic Association

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Executive Summary

Health plan prior authorization (PA) requirements have proliferated over the last decade, with patient exposure to PA increasing across nearly all medical service types, sites of care, and drug classes. In addition to generating greater physician burden and operational costs for healthcare providers, PA places patients at risk for harmful outcomes by delaying care or requiring the use of less efficacious therapies. Gold card programs, which offer exemptions to PA requirements to physicians with a track record of quality care and proper documentation, has been considered as a potential solution that would make the PA process more efficient and effective.

To date, 5 states have enacted gold card laws and several payors have voluntarily implemented gold card programs. This document summarizes programs that have been implemented across states and evaluates the effectiveness of such programs. Overall, the potential benefit of many gold card programs to date has not come to fruition, largely due to flaws in program design and failure to address fundamental elements of how plans implement PA requirements.

Gold card requirements can be a key part of comprehensive PA reform and alleviate administrative burden. However, policy must be shaped in a way that ensures physicians are able to qualify for programs and that regulators are able to appropriately oversee and define key elements of plans' program implementation. Such policy, alongside reforms that ensure PA requirements are clinically appropriate, applied in a parsimonious fashion, and made more efficient for physicians who do not qualify for a particular service, will support improved care delivery, patient outcomes, and physician career satisfaction.

Acknowledgements

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¹ American Medical Association. Prior Authorization Physician Survey. 2023. Available here.

Prior Authorization Background

Prior authorization (PA) is a utilization management practice which health insurers use to reduce potentially unnecessary costs associated with high-cost treatments and prescriptions. More often than not, prior authorization serves as a barrier to timely access to care or therapies.² Insurers determine if a medication or service is "medically necessary" based on criteria they establish, and will approve or deny the prior authorization request based on such metrics. Health plans suggest that evidence-based, properly implemented prior authorization programs should promote use of therapies that are most likely to be safe and effective, while minimizing waste.³ However, the proliferation of prior authorization requirements in recent years, across medications, medical items, and services, and exceptionally high approval rates that reach 94% in the Medicare Advantage market, indicate that prior authorization may typically be unnecessary.⁴

Over the last decade, plan use of prior authorization has expanded dramatically, having detrimental impacts on patient outcomes and physician administrative burden. In the Medicare Advantage (MA) market, plans have increased their application of PA across nearly all medical items and services, with some of the most dramatic increases in patient exposure to PA taking place with psychiatric services; diagnostic procedures, labs, and tests; physician administered drugs; and inpatient hospital services.⁵ Plans have also widely expanded PA requirements for pharmacy drugs. An analysis of MA formularies and plan data found that the share of Medicare Part D beneficiaries exposed to prior authorization requirements for non-specialty brand drugs increased from only 40% in 2018 to 80% in 2020.⁶

A similar trend has taken place in commercial insurance markets, reflecting that regardless of the type of insurance coverage patients have, they are increasingly subject to PA. An analysis of commercial plan formularies found that the share of brand drugs covered with open access, meaning without utilization management requirements, decreased across every therapeutic area analyzed.⁷

Application of prior authorization has a direct impact on patient outcomes. A 2021 survey of gastroenterologists found that nearly half of their respondents reported a patient experiencing a serious adverse event due to prior authorization related care delays⁸. In an American Medical Association survey, 88 percent of physicians reported that prior authorization interfered with the continuity of care for their patients⁹. Additionally, 94% of respondents report that PA results in care delays and 78% of physicians report that PA leads to treatment abandonment. These delays and

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² Fugelsten Biniek, Sroczynski. "Over 35 Million Prior Authorization Requests Were Submitted to Medicare Advantage Plans in 2021." Kaiser Family Foundation. February 2, 2023. Available here.

³ Academy of Managed Care Pharmacy. "Prior Authorization." Available <u>here</u>.

⁴ Fugelsten Biniek, Sroczynski. "Over 35 Million Prior Authorization Requests Were Submitted to Medicare Advantage Plans in 2021." Kaiser Family Foundation. February 2, 2023. Available here

⁵ Neprash and Mulcahy. "The Extent and Growth of Prior Authorization in Medicare Advantage." *Am J Manag Care.* 2024;30(3):e85-e92. Available here.

⁶ Kyle MA, Dusetzina SB, Keating NL. Utilization Management Trends in Medicare Part D Oncology Drugs, 2010-2020. *JAMA*. 2023;330(3):278–280. Available here.

⁷ Avalere Health. Utilization Management Trends in the Commercial Market, 2014–2020; 2021. Available here.

⁸ Shah ED, Amann ST, Hobley J, Islam S, Taunk R, Wilson L. 2021 National Survey on Prior Authorization Burden and Its Impact on Gastroenterology Practice. Am J Gastroenterol. 2022. Available here.

⁹ American Medical Association. Prior Authorization Physician Survey. 2023. Available here.

interruptions can result in serious health consequences, which may in turn result in additional procedures or interventions. The risk of adverse events resulting from PA grows as plans apply PA to an ever-growing number of services.

Negative health outcomes resulting from care disruptions caused by PA are varied. There are occasions when patients are obligated to receive alternative, less effective therapy¹⁰, or in some cases, care delays result in abandonment of treatment altogether. Adding prior authorization requirements to a patient's established drug regimen has been found to increase the probability of discontinued and delayed care¹¹. When patients cannot access their medications or receive the care recommended by their physician, their condition could worsen and require more significant and costly treatment as a result.

In addition to creating access challenges, physicians face substantial administrative burden due to PA. This burden has been found to be a driver of burnout.¹² Physicians and their staff spend an average of 12 hours per week completing prior authorization requirements. These requirements also drive substantial costs, as 35% of physicians report needing to hire staff to work exclusively on PA.

The burden associated with PA has intensified in recent years, and new innovations, such as platforms using artificial intelligence (AI), have enabled plans to more easily expand their use of prior authorization to a larger volume of services. Additionally, these AI-driven PA tools rely on proprietary data and algorithms, and their increasing use has even prompted Centers for Medicare & Medicaid Services (CMS) to issue guidance to plans on how use of these software may be inconsistent with federal rules related to PA.¹³

In light of the increasing number of procedures and medications being subject to prior authorization, and the resulting negative patient outcomes and physician burnout, lawmakers have taken several steps to ease the burden of prior authorization while maintaining appropriate oversight of healthcare utilization. However, policy action to date has been limited, and comprehensive actions to limit the abuse of prior authorization requirements are needed.

Federal Action to Address Prior Authorization

In recent years, federal action to address prior authorization has been limited to agencies using existing authorities to implement rules that streamline prior authorization or ensure requirements comply with health plans' coverage obligations.

CMS has taken several steps to streamline prior authorization in recent years. As of January 2021, CMS requires Part D plan sponsors to support electronic prior authorization (ePA) by

¹⁰ Association for Clinical Oncology. ASCO Prior Authorization Survey Summary. 2022. Available <u>here</u>.

¹¹ Kyle, Michael Anne and Keating, Nancy L. Prior Authorization and Association with Delayed or Discontinued Prescription Fills. Journal of Clinical Oncology. 2023. Available here.

¹² Rao, Sandhya K., Kimball, Alexa B., Lehrhoff, Sara R., Hidrue, Michael K., Colton, Deborah G., Ferris, Timothy G., and Torchiana, David F. The Impact of Administrative Burden on Academic Physicians: Results of a Hospital-Wide Physician Survey. Journal of the Association of American Medical Colleges. 2017. Available here.

¹³ Centers for Medicare & Medicaid Services. "Frequently Asked Questions related to Coverage Criteria and Utilization Management Requirements in CMS Final Rule (CMS-4201-F)" February 6, 2024. Available here.

utilizing the National Council for Prescription Drug Programs (NCPDP) standards for ePA transactions. In 2024, CMS also finalized its Promoting Interoperability and Improving Prior Authorization Processes rule, which implements a broad range of prior authorization reforms, requiring Medicare Advantage plans, Medicaid and CHIP managed care, and qualified health plans on Affordable Care Act exchanges to comply with prior authorizations requirements for medical items and services that includes:

- Support electronic prior authorization transactions via prior authorization application programming interfaces;
- Comply with newly established decision timeframes;
- Provide a specific reason to providers when PA requests are denied; and
- Require information regarding PAs to be shared with physicians and patients.¹⁴

CMS also took action in its CY2024 Medicare Advantage and Part D rule to prevent plans from abusing prior authorization by clarifying that MA plans' coverage requirements must be consistent with traditional Medicare benefits; requiring that coverage criteria and PA decisions be consistent with CMS national coverage determinations and local coverage determinations or based on publicly available literature. As a result, MA plans may no longer use proprietary data for developing coverage criteria and making coverage decisions for medical items and services in MA. Additionally, the 2024 rule requires that adverse decisions must be reviewed by a relevant expert in the service being denied, and it established continuity of care requirements for when beneficiaries change plans. Several of these changes were primarily driven by findings of the Department of Health and Human Services Office of the Inspector General investigation that MA plans inappropriately denied services that would otherwise be covered under traditional Medicare, a practice inconsistent with program requirements. Ma

While the above changes are important steps forward to prevent misuses of prior authorization, more can be done to limit beneficiary exposure to PA and reduce the burden it places on physicians. Because the vast majority of PAs are approved, efforts could focus on limiting the scope of PA requirements to those services where approvals are not routine, and grant physicians with a track record of appropriate prescribing relief from requirements. Programs such as gold card exemptions seek to achieve this.

Gold Card Program Background

Gold Card programs are designed to ensure that physicians who have a track record of appropriate utilization and proper documentation are waived from needing to obtain PAs for specific drugs, items, or services for which they are regularly approved. Such programs have the potential to reduce the time practices spend on PA and allow physicians to focus on patient care.

¹⁴ Centers for Medicare & Medicaid Services. "CMS Interoperability and Prior Authorization Final Rule CMS-0057-F." January 17, 2024. Available here.

¹⁵ Centers for Medicare & Medicaid Services. "2024 Medicare Advantage and Part D Final Rule (CMS-4201-F)." April 5. 2023, Available here.

¹⁶ U.S. Department of Health and Human Services Office of the Inspector General. "Some Medicare Advantage Organization Denials of Prior Authorization Requests Raise Concerns About Beneficiary Access to Medically Necessary Care." April 27, 2022. Available here.

Gold card programs typically require physicians to achieve a certain PA approval rate to be granted an exemption, which lasts for a defined period of time. Gold card programs are distinct from automated approvals of electronic prior authorization transactions as systems that automate review of PA still require physicians to submit a request. Overall, such programs need to be carefully designed to ensure that physicians can meet requirements for PA exemptions, and to ensure that plans can appropriately administer and manage them. Considerations include but are not limited to:

- Methodology for identifying individual providers for exemptions;
- PA approval thresholds at which physicians would qualify for waiver or exemption from PA:
- Duration of exemptions;
- Scope of the program, including applicability across drugs, items, and services;
- Methodology for tracking approvals for certain services, particularly when multiple CPT codes may be reported together, and managing notifications; and
- Approach to expirations, rescissions, and/or renewal of waivers.

Legislators at the state and federal levels have introduced legislation to require payors to implement gold card programs to address the growing concerns from prior authorization burdens. Several state bills have been enacted into law.

In July 2023, the *GOLD CARD Act* was reintroduced in the U.S. House of Representatives. The legislation would exempt physicians from prior authorization requirements under Medicare Advantage plans for medical items and services if at least 90% of the physician's requests for the item or service were approved during the previous plan year. Although the legislation would permit plans to rescind an exemption, Medicare Advantage plans must demonstrate that fewer than 90% of claims submitted during a 90-day plan period would have received prior authorization under their requirements. This 90-day review must be extended until at least 10 claims are ultimately provided. Additionally, the legislation would require recissions to be reviewed by physicians who are in the same or similar specialty as the requesting physician, and have knowledge of the specific service in question.

At the state level, Louisiana, Vermont, and Michigan all passed legislation requiring plans to implement their own gold card program. The states did not dictate any threshold for approval rating or length of coverage, leaving the details to each plan.

Texas and West Virginia both passed gold card legislation establishing a threshold for approval and exemption duration. The West Virginia gold card program, as amended by 2023 legislation, went into effect in July 2024.

Evaluation of Gold Card Programs Currently in Effect

The 5 states that have implemented gold card laws, as of 2024, have taken varying approaches. While some states have taken highly prescriptive approaches that define how plans must implement key elements of their exemption programs, others enacted legislation that grants plans greater flexibility. Initial research suggests that even states with more prescriptive approaches, such as Texas, still have gaps in their design that limit the law's impact and enable plans to grant very few exemptions. To date, the only states with meaningful data on outcomes of their laws are Texas and Vermont.

Texas Gold Card Law

The Texas legislature passed House Bill 3459 in 2021 which requires that health plans regulated by the Texas Department of Insurance (TDI), including health maintenance organization, preferred provider organization, and exclusive provider organization plans, must implement gold card programs to provide exemptions from PA. The law, which went into effect in October 2022 following promulgation of implementing regulation by TDI, is the most comprehensive of state gold card laws passed to date. ¹⁷. The law requires that physicians must be approved for a drug, service, or procedure at least five times in a six-month period and maintain a 90 percent approval rate. In effect, if a physician submits between 5 and 9 prior authorization requests to an applicable plan for a specific procedure or medication in six months, 100 percent of those requests must be approved. If a physician meets the criteria for the exemption, the plan must notify the physician of their status. The plan may rescind the exemption after at least six months if a retrospective review of claims finds the physician no longer meets the criteria.

TDI does not restrict how payors define PA requirements, and the term "particular health care service" is defined in the law as "a health care service, including a prescription drug, that is subject to preauthorization as listed on the issuer's website" 18. As a result, plans retain substantial flexibility in how they establish coverage criteria and make determinations.

When determining eligibility for a gold card exemption, payors evaluate providers based on "eligible preauthorization requests". Statute dictates that preauthorization requests that are eligible for evaluation are not pending appeal and have an outcome of either approving the health care service, including a service that was approved upon appeal, or issuing an adverse determination for the health care service. Exemptions apply to care ordered, referred, or provided by the treating provider. For example, if an ordering physician receives an exemption from a payor for physical therapy, medications, or services, then the exemption extends to the provider rendering care.

In 2023, the Texas Department of Insurance presented findings to the National Association of Insurance Commissioners on a survey it conducted after the initial implementation of its gold card program. The survey found that only 4% of physicians met the threshold for evaluation to receive

¹⁷ State of Texas. 28 TAC §§19.1730 - 19.1733. Available here.

¹⁸ State of Texas. 28 TAC §§19.1730 - 19.1733. Available here.

¹⁹ Rule. §19.1730

²⁰ Rule §19.1731(d) and (e)

a gold card for one or more services, and only 3% of physicians ultimately received an exemption. However, prior to the law's implementation, PA was applied to 21% of claims and an average of 85% of prior authorization requests were approved. TDI notes the impact of the law has been smaller than expected, indicating that:

- The evaluation period for determining exemptions should be lengthened;
- The granularity of a "particular health care service" should be reduced;
- The threshold for 5 PAs should be reduced; and
- PA data should be combined across plans, including those not subject to the gold card law, to base determinations on more holistic data on providers' prescribing practices.²¹

Additionally, the high approval rate for PAs prior to the law's implementation, and the incredibly low number of physicians who received a gold card (3%) indicate that plans have likely changed prior authorization practices following the law's implementation in a manner that limits qualification.

Additionally, as noted by TDI, some physicians may meet or exceed the 90% approval threshold for a service, but they may not reach the minimum five requests in six months for the plans to be subject to the law. Payors have access to data on physician prior authorization approval rates for all plans they administer, not just the plans covered under the gold card law. Future policy should consider lowering the request threshold of five, increasing the time frame from six months to a year or 18 months, and having payors combine data from all plans, not just those subject to this law.

West Virginia Gold Card Law

In 2019, the West Virginia legislature passed HB 2351 which enacted comprehensive prior authorization reforms, including requirements for plans to implement electronic prior authorization, as well as requirements for plans regulated by the state department of insurance to implement gold card programs.²² The legislation was amended in 2023 by SB 267²³ and went into effect on July 1, 2024. The law applies to most health plans within the state and requires issuers to grant providers an exemption from PA if they perform an average of 30 procedures a year, and in a six-month timeframe receive a 90% approval rate for that particular service. Gold cards must be valid for at least 6 months, and plans must notify providers when they are approved for a gold card. Based on findings from Texas' gold card law, this policy is likely to have a limited impact as requirements are more stringent than the Texas policy.

Louisiana Gold Card Law

In June 2022, Louisiana passed SB 112 which requires health insurance issuers regulated by the Louisiana Department of Insurance to develop plans for the selective application of prior authorization. The law simply requires each issuer to submit filings to the state by July 1, 2023, with a description of their programs that includes criteria for participation, applicable services and

²¹ Bowden, Rachel. "Texas' "Goldcarding" law HB 3459 (2021)". Texas Department of Insurance. Presentation at National Association of Insurance Commissioners Summer National Meeting. 2023. Available here.

²² State of West Virginia. West Virginia Insurance Bulletin No. 21-08. Available here.

²³ West Virginia Legislature. SB 267. Available <u>here</u>.

procedures, and the number of providers participating in the program. Each of these elements is up to the plan to determine, as the state does not set clear requirements around program design. Additionally, the requirement does not apply to pharmacy benefits.²⁴ As a result, this policy will likely have limited impact.

Vermont Gold Card Law

Vermont has taken a unique approach to the gold card program by only requiring certain plans to implement pilot programs for modifying PA requirements. Under Act 140, Vermont required all health insurers with more than 1,000 covered lives in the state to implement a pilot gold card program, and the law granted plans substantial flexibility in designing their program requirements, including approval thresholds; durations for exemptions; and applicable drugs, items, and services. The law simply required plans to implement pilots and report findings to the state by January 15, 2023.²⁵

In late 2023, the Vermont Department of Financial Regulation submitted a report to the legislature outlining findings from implementation of Act 140. The report noted that the law had little impact as, pilots "were either so narrowly crafted that no providers qualified, or exempted a wide swath of procedures, medications, or providers—making it difficult for a provider to determine whether they even qualified for the gold carding pilots." The policy also notes that "all insurers oppose expanding the gold carding pilots." The lack of success of the pilots is likely attributable to the lack of clear program requirements, guardrails, and oversight within the enacted legislation.

Michigan Gold Card Law

Michigan passed a comprehensive prior authorization reform bill in 2022 which contained a provision requiring plans to implement a gold card program. ²⁷ However, the legislative language is exceedingly broad. It states that plans "shall adopt a program, developed in consultation with health care providers participating with the insurer, that promotes the modification of prior authorization requirements of certain prescription drugs, medical care, or related benefits," based on

- Performance of providers with respect to nationally recognized evidence-based guidelines, appropriateness of care, efficiency, or quality measures;
- Involvement in risk-sharing arrangements; or
- Provider specialty, experience, or other factors.

While the law broadly applies to health plans regulated by the state department of insurance, limited information is available on the extent to which Michigan health plans have implemented gold card programs.

²⁴ State of Louisiana. Act No. 432 (SB 112). Available here.

²⁵ State of Vermont. Act 140. Available here.

²⁶ Arduengo, Sebastian. Letter to Vermont House Committee on Health Care and Senate Committee on Health and Welfare. November 22, 2023. Available here.

²⁷ State of Michigan. Senate Bill No. 247. 2022. Available here.

Voluntary Private Payor Programs

Some private payors have independently chosen to implement gold card policies. However, the impact of these policies is varied. Many tend to have limited impact on the alleviation of administrative burden due to stringent requirements around how procedures are defined, approval thresholds (sometimes exceeding 95%), and applicability to drugs. One case study notes success of a gold card program within a health system. However, the case study notes that the plan required use of an approved clinical decision support software to participate in the program. The annual cost of a license for the software is \$130,000, which would make participation in the program inaccessible for any small provider group, and even cost-prohibitive for many hospitals.²⁸ Overall, voluntary adoption of gold card programs among private payors is not widespread, and many programs in place have limited benefit to physicians, predominantly due to the requirements imposed by the plans.

Approaches to Prior Authorization Reform and Expansion of Gold Card Policies

As prior authorization burden continues to increase, comprehensive policy that limits how plans apply PA requirements is needed. If gold card programs are well-designed with clear parameters, this can be an important component in reforming prior authorization. Such programs recognize plans' need to apply PA on certain services to ensure quality and appropriate resource use, while also protecting physicians who deliver high-quality care and have a track record of proper documentation. However, gold card programs should be pursued alongside other reforms that address, at a more fundamental level, how plans apply PA. It is likely that gold card programs' effectiveness to date has been limited because of the substantial flexibility plans retain in establishing PA requirements and coverage criteria – enabling them to circumvent newly established requirements by:

- Modifying coverage criteria for drugs, items, or services in a manner that reduces approval rates and limits qualification;
- Defining services in a manner that makes it more likely for certain requests to be denied;
- Expanding the list of services subject to PA, reducing the overall benefit of gold cards; and
- Imposing more burdensome documentation requirements.

As a result, gold card policies should ensure that the following are integrated in their design:

- Approval rates and volume thresholds must be appropriate to ensure physicians can qualify;
- Data used to determine qualification should include physicians' PA requests to an issuer across plan types and markets;
- Qualification periods must be long enough to enable physicians to perform a sufficient volume of a particular service; and

²⁸ Nair KV, Stuursma L, Eigenbrod M, Cremeen D, Ahmed A. Gold Carding Policies: Reducing the Barriers Between Payers and Providers. Neurol Clin Pract. 2024 Apr;14(2):e200256

 Regulatory bodies should be granted authority to define services for purposes of qualifying for a gold card to ensure that plans do not implement overly granular or restrictive requirements;

Additionally, the rise of artificial intelligence and predictive algorithms is enabling plans to review PA request more efficiently, apply PA to a greater number of services at reduced cost, and develop internal metrics for evaluating PAs, rather than relying on clinical guidelines and evidence.

To truly reduce the burden associated with PA, and limit potentially harmful application of PA requirements, lawmakers must enact comprehensive prior authorization reform that seeks to:

- 1. Ensure that PA policies and decisions by plans across markets are based on publicly available evidence and widely accepted clinical guidelines;
- 2. Protect patient safety by ensuring that any denials are determined by relevant specialists and clinical experts in the particular drug, item, or service being denied;
- 3. Drive automated processes for PA of drugs, items, and services;
- 4. Limit the application of PA and step therapy to drugs and services that are truly of concern for patient safety;
- 5. Prevent low-value PA policies that create burden and provide limited benefit to patient safety or appropriate utilization;
- 6. Ensure physicians with strong records of proper documentation and approval for PAs are granted relief from requirements.

Additionally, reforms must broadly apply across payors and include drugs, items, and services, in order to have meaningful impact. Taken together, the above reforms will improve patient care by ensuring safety, promoting appropriate utilization, allowing physicians to spend more time at the bedside, and reducing burnout.