Exploring Medicare Part D prior authorizations

CMS incorporates prior authorization in Medicare Part D administration to ensure access to appropriate drugs and control costs

Commissioned by the Blue Cross Blue Shield Association

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On January 1, 2006, the Centers for Medicare and Medicaid Services (CMS) launched the Medicare Part D drug program. Under this program, which provides prescription drug coverage to nearly 44 million Medicare beneficiaries,[1] CMS relies primarily on Part D plans (PDPs) and Medicare Advantage Prescription Drug Plans (MA-PDs), which we refer to in this paper as "plan sponsors," to administer the coverage.

To ensure the Part D benefit is comprehensive, CMS regulates the plan formulary and requires plan sponsors to offer a wide range of pharmaceuticals.[2] At the same time, to ensure the program is sustainable and affordable for beneficiaries, CMS allows plan sponsors to exclude some items from coverage. Within these and other Part D regulatory requirements, plan sponsors design their Part D benefits and plan features to appeal to prospective beneficiaries and ensure efficient, appropriate access to covered benefits. Prior authorizations (PAs) are one of many important and widely used features of Medicare Part D plans.[3,4,5]

The Blue Cross Blue Shield Association (BCBSA) commissioned Milliman to prepare this report, which highlights the primary purposes of PA, identifies some key CMS regulations pertaining to PAs, assesses the benefits and some challenges with the PA process, and identifies some potential future opportunities to improve the PA process. A PA requirement can be applied to a wide range of benefits, including procedures, tests, and prescription drugs. This paper's primary focus is on the use of PAs for prescription drugs within the Medicare Part D program.

What are the purposes of a PA?

The concept of PAs has existed for many years in the hospital setting, prior to managed care organizations adopting it to help manage the pharmacy and medical benefits. A PA requires the beneficiary or provider to present justification for coverage prior to the service or product being rendered or reimbursed by the plan sponsor.[6] In some cases, an authorization may be approved retroactively. Review of the PA request by a clinical pharmacist or physician gives the plan sponsor an opportunity to verify that the proposed services or products are appropriate for the member's unique situation and promotes safe, optimal, effective, and affordable care.[6,7]

Plan sponsors have a number of tools for managing benefits and spending, including formulary design and management and utilization management such as step therapy (ST), quantity limit (QL), and PA. In its 2019 report, the Medicare Payment Advisory Commission (MedPAC) noted that plan sponsors apply PAs for drugs that are expensive, potentially risky, subject to abuse or misuse, or are for experimental use.[8] Typically, plan sponsors use the PA to support two objectives: to determine that (1) the proposed drug is appropriate given the beneficiary's clinical status and the benefit design, and (2) the plan sponsor does not reimburse for inappropriate drug use. In addition to supporting these important objectives, benefits from the PA can include, but are not limited to the following:

- Reducing beneficiary out-of-pocket (OOP) cost as well as the cost to the plan sponsor.[9]
- Avoidance of duplicative drug therapies that could increase the risk of drug-drug or drug-disease interactions.
- Mitigating the risk associated with drug adverse events and their potential downstream complications and medical cost.
- Preventing the use of prescription drugs in conditions that are not recommended or medically indicated.[3]
- Reducing the use of drugs that are less clinically effective.[3]

Through the PA process in Medicare Part D, plan sponsors determine, based on pre-established clinical criteria, whether a prescribed drug is appropriate and necessary for the unique clinical characteristics of a given patient. A specific drug's PA use criteria is supported by evidence-based clinical criteria and/or the U.S. Food and Drug Administration (FDA)-approved indications.[2] Typically, the PA criteria are based on input from physicians, pharmacists, and other healthcare providers. Through application of these criteria, historical data, and use of clinical judgment, the plan sponsor makes a medical necessity determination of coverage for the requested PA drug.[10,11] Plan

sponsors often require PA for a limited set of both generic and brand name drugs.[10] Building PA into the formulary can encourage the use of generic drugs rather than brand name drugs, which usually results in lower beneficiary OOP cost. As reported by IMS Health, a prescription drug data mining company, the use of generic drugs can lower drug prices by 80%,[12] thus reducing both the beneficiary OOP cost and the plan sponsor cost.

The drugs subject to PA are typically those that are often high-cost, potentially subject to misuse, may be prescribed for off-label use, have multiple indications, or are overused. PAs are used by both types of Part D plan sponsors, PDPs and MA-PDs, but the extent to which they are used does not appear to vary. According to the 2017 MedPAC report to Congress, there was a 0% increase in formulary drugs requiring a PA between 2016 (26%) and 2017 (26%), across all PDPs, and a slight increase from 24% to 25% across MA-PDs, among the drugs listed on plan sponsor formularies.[13] Based on this data, one would assume there is a large percentage of prescriptions requiring PAs. However, according to the 2019 MedPAC report, in 2016, although one quarter of drugs required PA, only about 4% of prescriptions were rejected at the pharmacy for formulary restrictions, with PA being one of the reasons. However, the most common rejection reason was that the drug was not on the plan sponsor's formulary, followed by other restrictions to include QLs and STs, in addition to PA.

While the focus of this paper is on PAs, any discussion of PAs cannot overlook the relationship with other aspects of the Part D program, including the use of formularies and manufacturer drug rebates. In addition to using PA for drug use management, plan sponsors develop a formulary, which is a list of covered drugs organized by different cost-sharing tiers, to manage the prescription drug benefit, including considerations as to safety, efficacy, medical appropriateness, and cost-effectiveness.[5] Following CMS guidelines, the formulary is established from practicing physicians, physician specialists, and pharmacists. Within those guidelines the formulary cannot have selection bias and must have a minimum number of drugs by therapeutic category and class.[2] Formularies encourage competition within drug classes and promote utilization toward certain drugs that often have lower patient cost sharing.[5] Drug manufacturers pay rebates to plan sponsors for accessing the plan sponsor's formulary. The rebates are applied to reduce member premiums and are shared between the plan sponsor and CMS. The drug rebate process and rebated amounts are multifactorial and are often based on (1) accessing the formulary, (2) applying a drug specific PA or ST on non-rebatable drugs, (3) how the drug is positioned by OOP tiering, (4) the drug's market share, (5) a specified drug achievable outcome, and/or (6) the quantity of the manufacturer's rebate-assigned drugs dispensed.

However, not all formulary drugs and PAs are associated with rebates. Of note, the Office of Inspector General (OIG) report cited a 2019 Milliman study, which found that for CY 2016, 89% of Part D prescriptions had no rebates associated with them and only 36% of brand name drugs offered a rebate.[14,15] In the 2019 Medicare Trustees report and a 2013 report by the Kaiser Family Foundation (KFF), respectively, the effect of rebates to promote formulary drugs, which may or may not have a PA, yielded the following observations:

- 27.7% of total Part D drug cost in 2020 is estimated to be received as drug rebates, offsetting member premiums.[16]
- $15.50 was the average rebate amount applied to lower premiums in 2013.[17]

What are some of the CMS regulations that pertain to PA?

CMS regulations are intended to ensure plan sponsors cover Part D drugs for medically accepted indications, and utilize PA for those drugs with the highest likelihood of non-Part D covered uses. In some cases, plan sponsors may be able to use processes other than PA, like QLs and STs, to reliably determine appropriate coverage for a drug.[2,4]

CMS requires that a formulary be developed and reviewed by the plan sponsor's Pharmacy and Therapeutics (P&T) committee. Most of the P&T committee membership must be comprised of practicing physicians and/or practicing pharmacists. At least one practicing pharmacist and one practicing physician must be independent and free of conflict with respect to the plan sponsor and pharmaceutical manufacturers. The P&T committee must review the clinical appropriateness of the practices and policies for formulary management activities, such as PA.[2,4] All formularies list each drug's utilization management control(s) (PAs, STs, QLs) and have to be submitted to CMS for review and approval.

Although plan sponsors may base formulary management decisions on economic considerations that achieve appropriate, safe, and cost-effective drug therapy, their decisions must also be based on scientific evidence. An example of this might be incorporating the American College of Cardiology (ACC) cholesterol guidelines with the PA criteria for the new proprotein convertase subtilisin/kexin type

9 (PCSK9) inhibitors for high cholesterol. In the ACC guidelines, for some conditions, the PCSK9 inhibitors are not positioned over generic statins (cholesterol-lowering drugs), which have decades of proven scientific evidence with numerous cost-effectiveness outcomes and safety studies.[18]

CMS reviews, compares, and approves all PA policies, drug formularies, and other formulary management activities. It analyzes the PA processes and, in cases where a plan sponsor may fall outside of best practices, it may require the plan sponsor to provide a reasonable justification for its practices.[2]

Per CMS regulations, only a physician or pharmacist may issue a partially or fully adverse PA decision (i.e., a denial) based on a medical necessity determination.[2,4] The denial notice must be understandable to the beneficiary and provide the specific denial reason, considering the beneficiary's medical condition(s), disabilities, and special language requirements, if any. The denial notice must also describe any applicable Medicare coverage rule or Medicare Part D plan policy upon which the denial decision was based and any specific formulary criteria that must be satisfied for approval.[3] If the drug could be approved under the plan sponsor's exception rules, then the denial notice must clearly identify what is needed when seeking an exception and must adhere to these established determination and notification timelines: [2,4]

- 72 hours is the maximum time for the plan sponsor to review a standard PA request
- 24 hours is the maximum time for an expedited PA request from the prescriber, as directed by CMS

Prescribers can demonstrate why they believe a patient needs the requested drug by providing supporting documentation. If a notification timeline is missed, then the plan sponsor must forward the PA request to an independent review entity, which then makes the determination.[4]

CMS mandates that new enrollees be provided immediate access to a prescription drug for an ongoing drug therapy within the first 90 days of enrollment for non-formulary drugs and drugs with UM requirements (PAs). The member and their provider should use this one-time transition fill (up to a 30-day supply) to allow time for PA review and coordination of a therapeutically appropriate alternative formulary drug or request a formulary exception, without any disruption in drug therapy. Additionally, current plan members, who are negatively impacted by a plan sponsor's formulary change may also have access to a transitional refill.[4]

CMS measures plan sponsor quality performance each year through the Star Ratings program. Included in a Star Rating are Part D measures that address (1) drug plan customer service, (2) member complaints, problems getting services, and choosing to leave the plan, (3) beneficiary experience with the drug plan, and (4) beneficiary safety and drug pricing.[19] Beneficiary satisfaction ratings are a key component of plan sponsor Star Ratings. Plan sponsors with too many PA-related rejections at points of sale may receive beneficiary complaints that could potentially lower their Star Ratings. Thus, plan sponsors must balance their use of PA, which providers and beneficiaries sometimes view as an administratively challenging process, with the desire to promote appropriate and cost-effective care.

What are the benefits and challenges associated with PAs?

While we did not find any peer-reviewed studies quantifying their direct premium impact, PAs contribute to the affordability of Part D premiums and lowering of OOP costs by reducing unnecessary or inappropriate utilization, increasing rates of generic drug use for common chronic conditions, and potentially increasing adherence to needed treatment as found in a study by Semilla, et al.[20]

PAs have the potential to safeguard members. For example, PA applies additional scrutiny to the prescribing of drugs that are subject to misuse. A study by researchers at the University of Pittsburgh compared the opioid abuse rate for Medicaid populations subject to different levels of prior authorization. The two opioid PA groups consisting of a low PA group (plans that required PA for one opioid) and a high PA group (plans that required PA for multiple opioids) were 7% and 11%, respectively less likely to have members develop opioid abuse compared to the members enrolled in Plans not using a PA for opioids.[21] Another study on opiate use showed a 15% decrease in the average monthly prescribing of opioids following implementation of a health plan-wide opioid PA program.[22] Overall, promotion of PA to help address the high risks associated with opioid adverse drug events (ADEs) and abuse, while balancing the need for pain management, can lead to improved outcomes for the beneficiary.

As another example of how PA can safeguard members, the elderly and chronically ill are especially susceptible to using a high volume of drugs, also referred to as medication overload, and high-risk drugs.[23,24] CMS recognizes these risks and requires plan sponsors to manage them.[25] Plan sponsors can omit some high-risk drugs from the formulary. However, in cases where these drugs are on the formulary, a ST or PA can be applied to evaluate the medical necessity of these drugs. We do know that the PA process adds safeguards when prescribing high-risk drugs.[3,10]

The PA process can be time-consuming to stakeholders, including patients, physicians, and pharmacists. It has been documented that PA stakeholders have incurred obstacles in administering care, seen increased administrative costs and staff workload, experienced impediments to efficiency, reported decreases in actual time spent on patient care, and observed delays in beneficiary access to therapy.[26,27] This has the potential to lower satisfaction for the beneficiary and providers. To some physicians, it seems that the plan sponsors are trying to intrude on the physician's autonomy and that it is an overall unwarranted burden.[13]

At least one published peer reviewed study exists that reported on the impact of PAs on patient outcomes. In an effort to document the effect of PAs, Park et al. conducted a systematic literature review of formulary restrictions (specifically PA and step therapy) with mixed results on the studied patient and payer outcomes. They highlighted that, in the Medicare population studies (N = 27), 14 studies (51.9%) showed that PAs had a positive association on the studied outcome measurements—drug and medical costs, use of the emergency room (ER) or hospital, patient satisfaction, clinical outcomes, medication adherence, and drug utilization. In the review, there were nine studies (33.3%) and four studies (14.8%), respectively, reporting negative or neutral associations of PAs on the studied outcome measures.[28] In conclusion, the authors observed these results could be impacted based on the type of payer, drug class, and disease state. They suggested that, when making formulary decisions, these variables will need to be factored into the process.[31]

Bergeson and colleagues conducted a retrospective study and found higher plan-paid healthcare costs (overall and medical alone) among members who requested a Type 2 diabetes medication requiring PA, but never received it, compared with those who qualified for and received the requested medication.[6] The authors concluded that failure of a member to take medication deemed necessary by his or her physician could translate to inadequate control of the diabetic condition and result in an excess of resource utilization and costs for treating the disease and associated comorbidities.[6]

Opportunities to improve the PA process

For many providers the top most concerns with PAs is inadequate communications between the plan sponsor and providers. The providers believe this leads to delays in access.[13] Wide adoption of PA innovation (e.g., electronic PAs) by physicians, pharmacies, and plan sponsors could help drive better results and adoption of the PA process.

Effective communication, including the use of electronic tools (e.g., those found at the Covermymeds website at https://www.covermymeds.com/main/), regarding PA among patients and physicians can reduce the burden on the physician. With better communications, providers can share their clinical judgements and patient data with the plan sponsor in near real-time manner. Communicating back to the provider, the plan sponsor can inform the provider of the coverage determination and possible next steps in the PA process. In the authors experience, proactive discussions among the patients, providers, and plan sponsor regarding PA requirements and processes can (1) decrease their frustration, (2) manage their expectations, (3) avoid delays in or abandonment of treatment by encouraging patience in the process, and (4) promote the patient to be an advocate for themselves by communicating with the plan sponsor.

Generally, widespread application of technology to the PA process in the medical industry has been slow as just 12% of PAs are fully electronic and only 36% partially electronic as of 2018.[29] Plan sponsors and physicians are in agreement to improve the transparency and efficiency of the PA process and avoid costly delays or abandonment in care, The Council for Affordable Quality Healthcare (CAQH) Index reported that the medical industry could save $417 million annually—with providers gaining the greatest share, at $278 million—by converting to electronic PA.[30]

Often, PA requirements are listed on the plan sponsor's website or provided upon request, which can be inefficient.[12,13] Ideally, to promote transparency and efficiency, plan sponsors should make PA requirements readily available to prescribers and beneficiaries. In an effort to make the PA process more efficient, plan sponsors understand that, for prescribers to adopt PA widely, the process needs to maximize the reliance on technology, streamlining the workflow, lowering the administrative burden, and improving transparency. Plan sponsors

are adopting feedback from prescribers and patients to incorporate the PA criteria and rationale with real-time access in an effort to improve satisfaction and efficiency. For example, incorporating the PAs into electronic medical records (EMRs) or point of care systems, or using cell phone text messaging, can benefit all stakeholders.[12,13]

CMS has introduced initiatives like the Real Time Benefit Tools (RTBTs), which can display patient-specific price information to clinicians writing prescriptions, and electronic PAs (ePAs) that should streamline the PA process. Medicare Part D beneficiaries were 57% less likely to receive prescriptions for high-risk medications when an ePA pilot was initiated in 2015.[30] Unfortunately, there is little other data on the cost-saving opportunity with the use of ePAs. However, it has been projected, as referenced above, that the medical industry could save $417 million from ePAs along with seven minutes saved per transaction per year.[33]

The healthcare industry is working with stakeholders on electronic automatic authorization criteria that could include targeting prescribers who practice evidence-based medicine. These prescribers will have automatic approvals of prescribed drugs requiring PA.[9,11,12] These tools will likely improve transparency, efficiency, and acceptance with providers.

Conclusion

The PA process, allowed and promoted by CMS, is a tool for the management of drug therapy in Part D. CMS regulates plan sponsors to ensure physician and clinical pharmacist involvement and use of evidence-based guidelines in the PA process. The Part D benefit provides beneficiaries with access to drug therapy with an established premium, specified cost sharing, and a published drug formulary. PAs contribute to premium affordability by encouraging usage of clinically appropriate and affordable drugs. PAs have been demonstrated to lower utilization of high-risk medications like opioids and to help keep member OOP costs down. Plan sponsors and other stakeholders should consider not only the impact of PA on reducing drug costs, but the broader implications for overall healthcare quality. While the PA process has some obstacles, among them low satisfaction with stakeholders, delays in access, and provider administrative burdens, there appears to be more collaboration between the industry groups, led by the American Medical Association (AMA) and America's Health Insurance Plans (AHIP), toward addressing these obstacles and evolving the PA process. To improve beneficiary and provider satisfaction, plan sponsors may choose to continue to invest resources to develop innovative solutions to streamline the PA process and improve transparency on the PA services.

Authors note: During the COVID-19 pandemic, many Part D Sponsors have waived or relaxed PAs and other utilization management requirements to streamline enrollee access to formulary drugs. CMS has encouraged this flexibility to reduce the administrative burden on beneficiaries, plans and providers. Payers will likely reinstate this function after this emergency period is lifted.

Caveats

This report was commissioned by the Blue Cross Blue Shield Association. This work is for the specific purpose of providing a review of Medicare Part D prior authorizations. This information may not be appropriate, and should not be used, for any other purpose. It is not a comprehensive systemic review of published literature, which might yield information different from what we identified. In developing this report, we relied on our knowledge and experiences along with documentation from CMS and other government sources to inform the reader of the role of the CMS's Medicare Part D benefit PA process. No portion of this report may be distributed, in whole or in part, to any other party without Milliman's prior written consent. Milliman does not intend to benefit or create a legal duty to any third-party recipient of its work even if we grant permission to distribute our work product to such third party. The materials in this document represent the opinion of the authors and are not representative of the views of Milliman, Inc. Milliman does not certify the information, nor does it guarantee the accuracy and completeness of such information. Use of such information is voluntary and should not be relied upon unless an independent review of its accuracy and completeness has been performed.

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