

Memorandum

To: Sam Watts
From: Dr. Sadhna Paralkar, Tami Kellam, Nicholas Beckman, Kenneth Vieira
Date: October 4, 2024
Re: Prior Authorization Review

Executive summary

Segal was asked to put together information on prior authorization (PA) – mainly its history, its impact on plan costs and how it impacts member care.

In this memo, Segal reviews the use of PAs by the North Carolina State Health Plan (SHP) in both the medical and pharmacy benefits. We discuss its current use and the changes that will occur when Aetna begins plan administration on January 1, 2025. Finally, we prepared a detailed review of PA, how it works, how it is used in various state health plans and some best practices.

As an overview, PA is a necessary component of managed healthcare. Its intent is to ensure that the treatment a patient receives is consistent and follows clinical protocols that are evidence based, with patient safety as a priority. PA also works effectively to curtail fraud, waste and abuse. Plan costs are lower when a health plan has utilization management (UM) programs in place, including PA. PA overall contributes positively to patient safety. The removal of PA would likely result in an increased rate of low-value care being administered and patient safety being compromised. It is even more evident in the pharmacy program, where there is a tremendous amount of waste, as well as the potential harmful effects of drug interactions.

That being said, PA is not a perfect process. Progress has been made toward reducing processing times and administrative burden on participants, but there are still obstacles to overcome.

Advantages of PA

- 1. Improve quality of care:** PA ensures that all physicians follow evidence-based medicine, which involves making diagnosis and treatment decisions based on research evidence, clinical expertise and patient values and preferences. PA also ensures that providers make informed choices for their patients based on their benefit plan design, which introduces additional accountability in the system.
- 2. Fraud reduction:** When thorough documentation is required, there is automatically a reduction in fraudulent practices by providers.

3. **Patient safety:** Sometimes patients seek treatment from multiple providers/channels (e.g., virtual providers). PA can help prevent the overuse of certain medications and procedures, which can be potentially harmful to patients.
4. **Cost control:** Treating physicians are typically oblivious of the cost of the treatment/drug. But when only the necessary and cost-effective options are adopted, there is an automatic reduction in cost of care. PA attempts to achieve that control. Research in 2023 found that PA reduces the use of preauthorized drugs by 25%, resulting in a 3% overall reduction in Medicare Part D spending.¹

If implemented correctly, i.e., ensuring no delays in care, and making easy online portals available to providers, thus reducing their administrative burden, the advantages of PA to the payer can easily outweigh its cons.

PA is not a perfect process, and the burden to providers is measurable. But removing PA would result in increased utilization, potentially expose plan participants to low-value care, decrease patient safety and potentially increase plan costs and participant premiums significantly above trend and inflation, as cited later in this memo.

Aetna has 40% fewer CPT codes subject to PA compared to Blue Cross Blue Shield of North Carolina (BCBS NC). With the SHP changing administrators in 2025 there should be less administrative burdens on members and providers.

Summary of recommendations to simplify PA:

- Request full de-identified, aggregated reporting on PA determinations (described in more detail later)
- Prohibit retroactive denials when care is preauthorized unless materially misrepresented
- PA should remain valid for at least one year, regardless of whether there is a dosage change
- PA should remain valid for the length of treatment for chronic conditions
- Require new health plans or administrators to honor existing PA for at least 90 days
- Remove \$500 penalty for failure to receive PA
- Consider removing PA for home-based services and inpatient hospice. Aetna does not require PA for these services.
- Consider removing PA for in-network dialysis
- Together with Aetna, consider a gold-card approach similar to other carriers for qualified practices that have consistently demonstrated adherence to evidence-based guidelines.
- Like the State's Pharmacy and Therapeutics (P&T) Committee, a more proactive involvement from the SHP is recommended to monitor the PA list that Aetna maintains. SHP's proactive involvement with Aetna's PA list and process will help drive efficiencies that may reduce redundancy in the process.

¹ B. Vabson, "Prior Authorization Reduces Net Costs of Medicare Part D," August 2023. Link: <https://www.aei.org/health-care/prior-authorization-reduces-net-costs-of-medicare-part-d/>. Accessed 24 September 2024.

PA: general overview

PA is a utilization management (UM) process used by health plans and insurers to determine if prescribed services, treatments or medications are both medically necessary and aligned with clinical coverage guidelines before they are provided. The intended goals of PA are to enhance patient safety, improve health outcomes and control healthcare costs. Costs are mitigated or eliminated by reducing overutilization, avoiding low-value care², and preventing the unnecessary use of expensive services or treatments when less costly equally effective options are available.³

PA is primarily used for high-cost or specialized services, such as elective surgeries, advanced diagnostic imaging and specialty medications. The process may also be employed alongside other UM tools including step therapy, preferred/nonpreferred medication lists and cost-sharing strategies. PA and UM enable health plans to enforce evidence-based standards of care, ensuring that covered treatments are necessary and effective.

North Carolina State Health Plan — PA experience

The North Carolina State Health Plan (SHP) received summary information from their vendors on their 2023 experience. Although the information may not be everything requested, the data provided was adequate and consistent with other studies. The following observations can be made:

Medical PA

UM processes resulted in \$6.68 Per Member Per Month (PMPM) savings for the medical plan; a 1.47% mitigation or savings worth approximately \$42M in the 2023 plan year. In 2023, the SHP processed 23.8M in-network claims. 3.9M claims were denied (16.5%). There were 562,993 PA requests and 94% of the PAs were approved. There were approximately 32.5K PA denials, and 85% of these denials were due to medical necessity. Denials that were appealed totaled 2.4%, or 819, and approved appeals totaled 48%, or 396. Only 2,195 PAs (0.4%) were submitted by the providers as urgent requests and determined within 72 hours. PA denials amounted to 0.83% of all denials for the SHP under the medical plan. The average turnaround time for PA requests was **1.31 days**; approvals averaged 1.3 days, and denials averaged 1.5 days to reach a determination.

BCBS NC provided the 2023 service category and number of approvals. They are listed in the table on the following page⁴. Note that the majority of the approvals, 87%, were for MRI/CAT scans.

² **Low-Value Care** refers to medical services, treatments, or procedures that provide little to no benefit to patients. This exposes patients to unnecessary clinical risk and results in wasteful spending. These services are often not supported by strong clinical evidence, may not improve health outcomes, and can be harmful. Examples include unnecessary diagnostic tests, over-prescription of medications, and surgeries that are not essential.

³ California Health Benefits Review Program, "Analysis: Prior Authorization in California," California Health Benefits Review Program, Berkeley, 2023.

⁴ Blue Cross Blue Shield of North Carolina, response to email request for data, 10/3/2024

Service	Approved
Diagnostic Medical	7,895
Durable Medical Equipment Purchase	693
Durable Medical Equipment Rental	628
Home Health Visits	2,151
Hospital - Outpatient	27
Licensed Ambulance	2
Long Term Care	29
Maternity	73
Medical Care	14,390
MRI/CAT Scan	459,168
Neonate Sick Stay	447
Pharmacy - Medical	18,121
Physical Medicine	1
Pregnancy Complication	10
Private Duty Nursing	15
Psychiatric	3,427
Rehabilitation	388
Skilled Nursing Facility	223
Substance Abuse	462
Surgical Procedure	17,440
Surgical Stay	3,396
Transplants	88
Total Approved (94%)	529,074

Additionally, BCBS NC provided the detail of denial reason and number of denials listed in the table below:

Detail of Denial Reasons	Denials
Appeal #1 Denial Upheld	403
Appeal #2 Denial Upheld	84
Appeal #3 Denial Upheld	20
Appeals - Denied Provider Level I	76
Cardiology Medical Necessity Denial	306
Cardiology Medical Necessity Denial - Facility	23
Denied - PA Provider Courtesy Review	151
DIM Investigational Denial - Facility	72
DIM Investigational Denial - Out of State Facility	22

Detail of Denial Reasons	Denials
DIM Medical Necessity Denial - Facility	2,672
DIM Medical Necessity Denial - Out-of-state Facility	373
Investigational	910
Investigational with Medical Necessity Criteria	345
MRM - Denied Provider Courtesy Review	308
Non-Covered Benefit	217
Nonpar Denied	4
Not Medically Necessary	4,725
ONC Medical Necessity Denial - Facility	60
ONC Medical Necessity Denial - Out-of-state Facility	8
ONC Medical Necessity Denial - Professional	75
PA Denied	1,368
PCR Denial Upheld-Facility	4
PCR Denial Upheld-Vendor	36
Vendor Investigational Denial	200
Vendor Medical Necessity Denial	20,042
Total Denials (6%)	32,504

The SHP participates in the following UM special programs through BCBS NC: Diagnostic Imaging Management (DIM), Medical Oncology, and Avalon Lab Management.

The DIM reviewed approximately 121,000 claims and resulted in 5,803 denials, or 4.8% of applicable claims. Only 232 denials (4%) were appealed. The appeals resulted in 44% (107) being reversed and approved; 28% (66) of the reversals were due to the provider giving additional requested information resulting in the PA Meeting Medical Necessity category. DIM accounted for approximately 26% of UM savings resulting in approximately \$12M in net savings or 26% of UM mitigated cost.

Medical oncology reviewed approximately 3,600 claims and resulted in 81 denials, or 2% of applicable claims. There were 21 denials (26%) appealed. The appeals resulted in 21% (17) reversals; 47% (8) of the reversals were due to the provider giving additional requested information resulting in the PA Meeting Medical Necessity. Medical oncology accounted for approximately 6% of UM savings, resulting in approximately \$2.7M in net savings or 6% of UM mitigated cost.

Avalon Lab Management employs both PA and automated policy enforcement (APEA). APEA resulted in \$10.4M in mitigated costs. PA resulted in \$3.4M in mitigated costs.

Pharmacy PA

The pharmacy benefit is administered by CVS Caremark. According to the CVS Calendar Year 2023 and 2024 Review, in calendar year 2023 there were over 7.6M total prescriptions. UM programs reviewed 306,000 claim episodes and resulted in 89,700 (29%) denials and/or approvals at a reduced quantity.

CVS Caremark reports that this activity resulted in \$124.5M PA-related mitigated cost and \$142.3M in savings due to other UM processes. These savings are *prior to rebates* or other member cost sharing. Rebates and other member cost sharing can reduce associated prescription costs by approximately 37%.⁵

Non-specialty PA & UM activity accounted for 3.7% of the total prescription count but resulted in a cost mitigation of 7.0% of the total gross pharmacy cost prior to rebates. PA, step therapy, generic step therapy, and non-specialty quantity limits accounted for approximately \$124.5M in net savings, at a cost of approximately \$2.3M in fees. The tables below aggregate the information provided by CVS related to these programs.⁶

PA, ST, GST, QL Episode Summary	Episode Count	Savings (net)
PA	161,376	\$63,843,699
Step therapy	21,790	\$20,268,839
Generic step therapy	278	\$85,809
Non-specialty quantity limits	100,801	\$42,748,822
Total episodes initiated	284,245	\$126,947,169

PA is utilized to reinforce the pharmacy policy for both step therapies and quantity limits. The SHP data highlights the potential disconnect between providers and health plans in general. Most prescriptions are not subject to PA; 90% of PA requests were triggered by a denial as shown in the table below.

PA, ST, GST, QL Episode Summary	Episode Count	%
Episodes initiated by a reject	256,208	90.1%
Episodes initiated by a PA	28,037	9.9%
Total episodes initiated	284,245	100%

⁵ CVS Caremark, "North Carolina State Health Plan Calendar Year 2023 and 2024 Review", May 2024

⁶ CVS Caremark, "Full Savings Appendix", May 2024

Providers only initiated PA for 0.4% of total processed prescriptions, and 90% of PA requests were in response to an initial denial of the prescription as written. Ultimately, 61% of initial denials classified as falling under PA did not result in a formal PA request. In 2023, there were 128k formal PA requests, resulting in a 75.8% approval rate. The table below summarizes the PA denial and approvals:

PA, ST, GST, NSQL Episode Summary	Episode Count	%
Episodes with PA – approval	97,129	75.8%
Episodes with PA – denial	22,907	17.9%
Episodes with PA – admin denial	8,181	6.3%
Total episodes with PA requested	128,217	100%

The SHP pharmacy data provided by CVS Caremark highlights the financial benefits but also the operational challenges of PA for the SHP. Approximately 100k prescriptions were potentially delayed because of an initial denial, due to the provider failing to submit PA properly on behalf of their patient. The PA denial rate does warrant review at 17.9%, but 2023 claims data were heavily impacted by prescribing of weight loss drugs (mainly GLP-1s) and incretin mimetic drugs for weight loss.⁷ We anticipate this to change in 2024.

Specialty guideline management and specialty quantity limits address a much smaller overall percentage, ~0.3%, of overall drug UM, but impact cost almost equal to non-specialty UM mitigating ~6.5% of total gross pharmacy cost prior to rebates. Specialty pharmacy rebates reduce total gross cost ~31%.⁸

SPA, SQL Episode Summary	Episode Count	Savings (net)
Specialty PA	24,657	\$94,061,302
Specialty quantity limits	483	\$24,508,563
Total episodes initiated	25,140	\$118,569,865

⁷ Anti-obesity agents and incretin mimetic agents comprised ~26% of all non-specialty episodes and resulted in \$93.3M in net savings before rebates, or ~73.6% of non-specialty drugs savings.

⁸ Pharmacy & Therapeutics Committee Meeting, “Overview of Specialty Pharmacy”, July 25, 2024

Specialty medications address a limited subset of drug classes. The following table outlines the classes, approval rates and pre-rebate savings.

Drug Class	Net Savings	Net Savings Per Episode	Approval Rate
Psoriasis	\$16,029,458	\$5,488	67.00%
Oncology	\$11,770,244	\$7,002	81.70%
Rheumatoid Arthritis	\$10,935,167	\$3,432	75.10%
Atopic Dermatitis	\$4,796,111	\$2,343	75.20%
Sleep disorder	\$4,612,633	\$25,206	54.60%
Pulmonary Arterial Hypertension	\$4,575,876	\$6,850	19.00%
Inflammatory Bowel Disease	\$3,073,962	\$8,962	59.20%
All Other	\$38,267,850	\$2,808	58.10%

PA is integral to specialty guideline management. As a separate program there is not a specific fee associated with PA alone as there is with non-specialty management. Specialty drugs are typically subject to policy requirements and are not the first step for most therapeutic protocols. As a result, providers are much more likely to request PA, as seen in the following table.

SPA, SQL Episode Summary	Episode Count	%
Episodes initiated by a reject	13,474	53.6%
Episodes initiated by a PA	11,666	46.4%
Total episodes initiated	25,140	100.0%

Nearly half of all specialty PA episodes are submitted by the provider. On average, specialty PA is approved 70% of the time. The table below outlines the provided data:

SPA, SQL Episode Summary	Episode Count	%
Episodes with PA – approval	15,617	69.7%
Episodes with PA – denial	4,741	21.2%
Episodes with PA – admin denial	2,039	9.1%
	22,397	100%

Specialty and non-specialty pharmacy combined mitigated \$243M in cost prior to rebates. With approval rates at 69% and 75%, it is clear that certain drug classes may be able to ease PA restrictions with further evaluation by the P&T committee. Pharmacy benefit managers (PBMs) are invested in the UM and PA process. It is typical for performance guarantees to be established requiring that 95% of episodes are resolved within 24 hours, 99% of episodes are resolved in 48 hours, and 100% of episodes are resolved in 72 hours, with a percentage of their admin fees at risk if they do not meet these requirements. Systemic enhancements will require collaboration between providers, health plans and PBMs to refine existing processes to be clearer and easier for providers to follow.

Overall PA impact

Overall, PA reduced the SHP costs by **\$166.5M net of fees** from CVS, DIM and Medical Oncology (approx. \$5.8M in combined fees).

BCBS NC reported \$2.9B in total payments for the medical and CVS reported \$1.8B in net payments (prior to rebates and member cost share worth \$797M) for the pharmacy.

Based on the information provided by BCBS NC and CVS, we conclude that medical PA resulted in 1.5% in net cost mitigation and pharmacy PA resulted in 6.8% net cost mitigation.

PA	Total Cost	PA Fees	Mitigated Cost (Net PA Fees)	% Savings
Medical ⁹	\$2.9B	\$3.5M	\$42M	1.5%
Pharmacy ¹⁰	\$1.8B ¹¹	\$2.3M	\$124.5M ¹²	6.8%
Total	\$4.7B	\$5.8M	\$166.5M	3.5%

⁹ Blue Cross Blue Shield of North Carolina, "State Health Plan Quarterly Meeting", 5/17/2024

¹⁰ CVS Caremark, "North Carolina State Health Plan Calendar Year 2023 and 2024 Review", May 2024

¹¹ Total gross pharmacy cost with rebates is \$1B; PA savings is calculated prior to rebate consideration

¹² Specialty Guideline Management & Special Quantity Limit Review and Specialty Copay Card are excluded; additional net savings of \$142.3M attributable to UM processes

General overview: medical policy and utilization management

Medical policy serves as the foundation of a health plan, guiding decision-making on what services, treatments and procedures are covered and under what circumstances. These policies encompass a wide array of guidelines, including coverage criteria, clinical standards, UM, preventive care and limitations or exclusions. PA is one UM tool that operates within the broader context of these medical policies.

PA acts as a control mechanism, ensuring certain healthcare services are reviewed for medical necessity and clinical appropriateness. This process maintains the integrity of healthcare delivery by promoting the use of appropriate treatments and mitigating risk of unnecessary and/or high-cost interventions. UM encompasses the processes by which health plans manage care to prevent overuse and promote cost-effective treatment.

While this memorandum will focus on PAs, it is important to understand that it is one process within a broader model of health plan policy and management. More on UM is in the appendix.

How does PA operate?

PA can be identified several ways within policy documents: prior review, preauthorization, precertification¹³, prior approval, prospective review, prior plan review, authorization review, and coverage review have all been used to refer to the exact process of PA. In operation, PA follows a predictable routine from the initial submission through the potential appeals process:

- Request submission
 - Provider or pharmacist submits a PA request to the health plan or insurer for a service, treatment or medication.
 - Relevant clinical information, such as diagnosis, medical history, and proposed treatment plan is provided with submission.
- Initial review
 - The health plan or insurer's UM team review the request to determine if the service meets the criteria based on medical policies and established clinical guidelines. Complex cases may be escalated to a medical director and/or clinical expert for further evaluation.
- Determination
 - The request is either approved or denied, or an alternative treatment plan may be suggested; typically a lower-cost alternative with established efficacy equal to the proposed treatment plan or prescribed medication.
 - The determination is formally communicated to the provider and the patient.
 - If applicable due to denial or modification an appeals process can be initiated by the provider and patient.
- Service delivery

¹³ Precertification is a related utilization management process that pertains typically to inpatient procedures or hospital stays. Precertification is used to evaluate if a service meets the plans' eligibility and coverage guidelines. It does not evaluate medical necessity or clinical appropriateness of a service, treatment or medication based on established clinical standards; however, in practice the terms are seen to be used interchangeably within health plan documentation.

- Once an approval or modification is accepted then service or treatment is provided, and the authorization is used in claims processing.
- Ongoing review may be necessary for certain long-term treatments or high-cost services.

How long does PA take?

The PA process typically ranges from 5-15 business days after the health plan or insurer has received all the required and relevant documentation. North Carolina has a state law governing PA known as N.C. Gen. Stat. § 58-50-61. Standard PAs must be determined and communicated within three (3) business days after receiving all necessary information and urgent or expedited appeals must be determined as soon as possible, no later than four (4) calendar days after receiving all required information.

The Affordable Care Act requires that non-federal governmental plans must comply with claims and appeals rules promulgated by the DOL under PHSA Section 2719. Urgent cases or approved expedited requests must be determined within 72 hours.

How long is a PA valid?

If a PA is approved, the approval may remain valid for a period ranging from 30 days to 1 year depending on the treatment or procedure. Procedures such as elective surgeries will typically be given a 30-to-90-day window for the PA to remain valid. Ongoing treatments for chronic conditions, like those requiring specialty medications for example, may be approved to remain valid for up to 1 year.

PA appeals process

In the event of a denial, the provider and patient have a clear appeals process to follow. There is a first-level appeal that can be filed typically up to 180 days from the initial denial notice. The first-level appeal is typically resolved within 30 days by an internal team of clinical experts and a medical director. If the first-level appeal is denied, then a second-level appeal may be initiated which may take up to an additional 45 days to resolve and is overseen by an external panel of third-party experts. After exhausting the first and second level appeal, the provider and patient may engage the State Department of Insurance (DOI) for an external review — the DOI will then convene an independent review organization to review the matter in full.

Once the DOI has made its determination, the matter is considered final for the appeals process. The external review may take up to 45 days. Depending upon when the initial appeal is filed, the standard appeals process may take as little as 30 days to as long as 10 months. Expedited appeals and external reviews are available when a patient's life is in jeopardy and each appeal level must be determined within 72 hours of the health plan, insurer, or DOI receiving the complete request and all applicable materials. An expedited appeal may take as little as a few hours and as long as nine days to exhaust the first, second and external appeals process.

Pharmacy policy and utilization management

Pharmacy policy PA follows the same operational process as medical policy PA, however in the context of UM of pharmacy policy it plays a more collaborative role in conjunction with other UM processes. Formulary management, quantity limits and step therapy, which may include generic substitution and therapeutic interchange as well as ongoing drug utilization review are integral to pharmacy UM. PA ensures medical necessity and clinical efficacy, as well as enforcing the formulary management guidelines and working in conjunction with quantity limits and step therapy policies. Pharmacy policy employs PA as an integral part of the broader UM strategy.

Formulary management

Formularies can be classified into either being open or closed. With an open formulary most drugs are available to patients with few exclusions; drugs that are considered non-formulary may cost more to obtain but do not typically require PA to do so. A closed formulary provides a strict list of drugs that fall into the formulary. Any drug that falls outside the formulary would require PA and potentially additional UM processes to be approved. Within either a closed or open formulary utilization may begin to be managed by adding a tiering system through which drugs are categorized based on factors such as cost, efficacy, and availability of therapeutic alternatives. For example:

Tier 1: Generic drugs — lowest cost

Tier 2: Preferred brand-name drugs — medium cost

Tier 3: Non-preferred brand-name drugs — high cost

Tier 4: Specialty medications — highest cost

Additional pharmacy utilization management

Once the formulary is set, it is continually reviewed and potentially revised based on actual drug utilization, typically every 6 to 12 months. Additional UM may be engaged within the context of the established formulary. These additional processes are step therapy, quantity limits, therapeutic interchange and PA.

- **Step therapy:** Requires patients to try lower-cost generic medications before more expensive or brand-name drugs if necessary.
- **Quantity limits:** Imposes limits on the amount of a medication that may be dispensed at one time.
- **Therapeutic interchange:** Recommend or requires switching from a prescribed drug to a therapeutically equivalent alternative that is more cost-effective.
- **PA:** Typically reserved for higher-cost or specialty drugs. Ensures that the drugs are used when medically necessary and after all other UM processes have been exhausted.

PA and pharmacy policy

The purpose of the PA within pharmacy policy is to ensure that prescribed medications are medically necessary, safe to use, cost effective, and align with the health plan's formulary. PA specifically targets high-cost drugs, medications with safety concerns, or treatments for which a less expensive alternative exists. PA ensures that the drugs are safe for the patient and that the patient meets the clinical criteria for using the medication.

By requiring PA for expensive and specialty medications, health plans can avoid unnecessary expenditures on treatments that may have lower-cost, equally effective alternatives. If the plan formulary is both closed and tiered, it will have drugs that require PA, ensuring that these drugs are used only when clinically appropriate and in line with all other formulary and UM strategies in place.

Electronic PA

Whether completing an electronic form via an online portal, uploading a PDF copy of a paper form or even faxing a paper PA form, the process of preparing and transmitting the required PA or pre-certification paperwork can be heavily manual and labor intensive for providers. Electronic PA (ePA) aims to streamline and reduce the administrative burden of the process as well as reduce the time it takes to make a determination once all required information has been submitted. Both BCBS NC and Aetna have provider portals for online submission of PA requests and for tracking.

When discussing ePA, it is important to understand the two forms the term may be referencing. Electronic PA post submission that uses automation solutions, such as natural language processing models (AI) combined with clinical data sets can effectively approve services or alternatively, electronic PA portals allow physicians to submit a PA request to be reviewed by a designated team manually.¹⁴ Electronic PA utilizing automated solutions make the approval more efficient, however it is important to understand that denials are not processed via automated methods. Any PA that cannot be approved automatically is sent for manual review. The exception for this would be when a treatment or drug is considered an excluded service or is considered experimental, then an automated tool may trigger a denial.

While efforts have been made to reduce the administrative burden on providers, systems and software still need to be improved.¹⁵ While providers do report that determinations are quicker utilizing ePA portals, a lack of real-time connectivity between systems requires manual entry of clinical information and required notations which are the most time intensive part of the process for providers.¹⁶

¹⁴ Availity, "Availity," 18 September 2024. <https://www.availity.com/>

¹⁵ S. G. Salzbrenner, C. McAdam-Marx, M. Lydiatt, B. Helling, L. Scheier and P. W. Hill, "Perceptions of prior authorization by use of prior authorization by use of electronic prior authorization software: A survey of providers in the United States," *Journal of Managed Care & Specialty Pharmacy*, pp. 1066-1196, 2022.

¹⁶ RTI International, "Evaluation of the Fast Prior Authorization Technology Highway Demonstration," AHIP, 2021.

North Carolina State Health Plan: detailed overview of utilization management

The North Carolina SHP currently uses UM processes within the medical and pharmacy Policies. The following listed processes are explained in detail within the state health plan benefits booklets and pharmacy formulary:

Medical — 2024 BCBS NC moving to Aetna in 2025

- PA (pre-service)/urgent PA
- Concurrent authorization/urgent concurrent authorization
- Retrospective authorization (post-service)
- Care management
- Continuity of care

Pharmacy — CVS

- Formulary management — closed formulary; tiered (8 tiers)
- Quantity limitations
- Step therapy
- PA

Additionally, the SHP allows for a standard appeals process, as well as a process to evaluate new technology and medications or procedures throughout the plan year. This list of services has not changed in the transition from BCBS NC to Aetna for 2025 in the plan booklet. Both BCBS NC and Aetna make their list of services subject to PA or pre-certification available online and both lists are updated quarterly. BCBS NC last updated their lists on July 3, 2024, and approximately 2,600 CPT codes require PA or pre-certification.¹⁷ Aetna last updated their lists on September 1, 2024, and approximately 1,600 CPT codes require PA or pre-certification.¹⁸

It should be noted that the SHP completed a review of its non-quantitative treatment limitations (NQTLs) under the Mental Health Parity and Addiction Equity Act (MHPAEA) in 2022. MHPAEA has specific rules for NQTLs, limits that otherwise affect the scope or duration of treatment, such as medical management tools (e.g., PA requirements). Specifically, under the MHPAEA regulations, a plan or issuer may not impose an NQTL on MH/SUD benefits unless any processes, strategies, evidentiary standards or other factors used in applying the NQTL to MH/SUD benefits in a classification are comparable to, and are applied no more stringently than, those used in applying the limitation with respect to Med/Surg benefits in the same classification. NQTLs such as PA requirements should continue to be monitored, particularly with the transition to Aetna and the release of new MHPAEA regulations to be effective in January 2025.

¹⁷ Blue Cross Blue Shield of North Carolina, "Services and CPT codes," 18 September 2024. <https://www.bluecrossnc.com/providers/policies-guidelines-codes/cpt-service-codes>.

¹⁸ Aetna Inc., "Precertification lists," 18 September 2024. <https://www.aetna.com/health-care-professionals/precertification/precertification-lists.html>.

PA and the state health plan

For in-network care, providers are responsible for requesting PA and seeking certification for applicable procedures, treatments, and medications. In-network providers, per the terms of their network agreement, are contractually obligated to conduct the PA process. The exception for this is for providers from Veterans Affairs (VA) and military providers are exempt from having to seek PA on behalf of their patients.

Out-of-network providers are not contracted with a network and are not responsible for requesting PA or certification for patients. It is the patient's responsibility to pursue PA and/or certification when utilizing out-of-network providers. The provider may choose to assist with the process, but they are not contractually obligated to do so.

If a provider fails to properly obtain a PA and a service is performed and subsequently denied the provider will not receive payment per their network agreement from the health plan or Insurer. It is standard practice for providers to ask prospective patients to sign financial responsibility waivers; these waivers inform patients that services may not be covered and that they, the patient, will be financially responsible for the cost of the service. Providers are not obligated by their network agreements to limit the patient's liability in the event of administrative oversight, however, catastrophic, and/or continuous failure to adhere to network agreements could cause them to lose their status with the network. In addition to denial of services, failure to obtain PA and certification will result in a \$500 penalty for the member patient.

Health plan services subject to PA

Per the 2024 and 2025 SHP booklets, the following medical and pharmacy services are subject to PA:

Medical services subject to PA

Diagnostic services

- Laboratory, radiology, and other diagnostic testing
 - CT scans, MRIs, MRAs, PET scans
 - Specialty (complex) labs, advanced diagnostic testing, molecular pathology, therapeutic drug monitoring

Urgent care centers, emergency rooms, and ambulance services: Non-emergency air ambulance services

Family planning: Extension of inpatient hospitalization longer than 48 hours after a vaginal delivery or 96 hours after cesarean section.

Facility services

- Inpatient admission, except emergency care and maternity care (detailed above in family planning)
- Skilled nursing facilities

Other services

- Medications administered in an outpatient setting requiring provider administration
- Gene and cellular therapy & testing
- Dental surgery covered under medical plan
- Durable medical equipment
- Cochlear implants
- Home health care
- Home infusion therapy services
- Inpatient hospice services
- Bariatric surgery
- Private duty nursing
- Prosthetic appliances

Surgical benefits: Surgical procedures, including those that are potentially cosmetic

Temporomandibular joint (TMJ/TMD) services: If surgery is indicated

Transplants: All transplants and related care

Behavioral health

- Inpatient admission
- Residential treatment facility
- Applied behavior analysis (ABA)
- Intensive outpatient programs

Pharmacy services subject to PA

Formulary overview

Comprehensive formularies, like the SHPs, must categorize and organize approximately 3,000 unique drugs, available in over 9,000 variations such as dosage, formulation (e.g., extended release), and form (e.g., tablets, liquids). Additionally, formularies must indicate non-covered medications. CVS typically updates their formularies on a quarterly basis. Specialty medications, chronic disease management, oncology treatment and organ transplants are all categories which can easily exceed \$500,000 per claimant per event.

Not covered

Based on the 07/2024 custom formulary, there are approximately 200 unique drugs that are not covered, and approximately 500 variations of these non-covered medications, approximately

6% of available medications. All not-covered medications have a covered analogue that is equally clinically effective and more cost effective.¹⁹

Step therapy and quantity limits

There are approximately 95 unique drugs subject to step therapy and 150 unique drugs subject to quantity limits. Quantity limits are used primarily when there are safety concerns related to misuse or overuse or abuse of a medication, such as opioids, or ADHD medications. Step therapy is also meant for managing over-prescribing of drugs that carry higher risk of side-effects or may be used experimentally for off-label purposes. Many drugs that carry a risk for abuse or addiction carry both quantity limits and step therapy requirements.

PA

There are approximately 190 unique drugs subject to PA within six separate tiers. Drugs within Tiers 1, 2, and 3 requiring PA may be lower cost but also may have serious side effects and over or improper prescribing could result in reduction in efficacy or even fatal interactions with other drugs. Tiers 4, 5, and 6 contain drugs with a high cost, but may also require complex administration, carry the risk of severe or life-threatening side effects, risk of treatment resistance if improperly administered, have limited alternatives as a last-line therapy or strict use for specific conditions.

2025: What is changing after moving to Aetna

There will be minor differences in the PA process moving from BCBS NC to Aetna. The BCBS NC booklet notes that the non-urgent PA process will be completed in a reasonable time and provides both three business days and up to 15 business days for a determination. In moving to Aetna, the booklet has removed the 15-day language and PAs will now all fall within the three-business-day period.

The table below compares the SHP PA list to Aetna's PA list. There are PA requirements for the state health plan that do not require PA with Aetna. This insight may help the SHP determine what services could be removed from PA requirements.

¹⁹ Department of State Treasurer of North Carolina, "2025 Open Enrollment Information: Active Members," 19 September 2024. <https://www.shpnc.org/2025-open-enrollment-information-active-members>.

Item	Aetna	SHP (Current)
Inpatient hospitalization	Yes, excluding hospice	Yes
Maternity	Yes, beyond standard length of stay	Yes, beyond standard length of stay
Infertility services	Yes	Yes
Ambulance	Fixed wing only	Non-emergency air wing only
Outpatient surgery	Only specific procedures	Yes, All
Dialysis	When participating provider starts a request and dialysis is to be performed at an OON facility	Not mentioned
DME	Only motorized wheelchairs and scooters	Yes, All
Gender affirmation surgery	Yes	Yes, all surgery is subject to PA
Infertility services	Yes	Not mentioned
Prosthetics	Yes, only specific lower limb prosthetics	Yes, all
Neurostimulator implantation	Yes	Not mentioned
Nonparticipating freestanding ambulatory surgical facility services when referred by a participating provider	Yes	Yes, all surgery is subject to PA
Inpatient hospice	No	Yes
Home health care	No	Yes
Private duty nursing	Yes	Yes
Reconstructive or other procedure that maybe considered cosmetic	Yes	Yes
Site of service	Yes, for specific services in outpatient hospital setting (not ambulatory surgical facility or office setting)	Not mentioned
PT/OT/ST	No	Not mentioned
High-tech radiology: MRI, CT scan, MRA, PET scan, interventional pain management	Yes-EviCore	Yes
Specialty (complex) labs, advanced diagnostic testing, molecular pathology, therapeutic drug monitoring	BRCA and whole exome sequencing	Yes-not defined
Attended sleep studies	Yes (Evicore)	Not mentioned
Radiation oncology	Yes via Availity	Not mentioned
Transplant	Yes	Yes
Cochlear device or implantation	Yes	Yes

Item	Aetna	SHP (Current)
BH inpatient confinement, partial hospitalization, ABA, residential treatment facility	Yes	Yes
Out of network	Yes	Yes

As previously noted, the Aetna precertification list is significantly less extensive than BCBS NC. [The Aetna Precertification list for Medical and Behavioral Health](#) is online.

For services that do not require precertification but do require evidence of medical necessity at the point of claim payment, there is an option for a pre-determination. A pre-determination is initiated by a member who wants to ensure a service is medically necessary prior to receiving the service.

As members transition to Aetna, some individuals may have existing PAs from their previous insurer (BCBS NC/PBM). If the current provider who prescribed the service or pharmacy is out-of-network, a transition of care (TOC) may be required. Aetna's standard TOC period is 90 days, during which PAs from the previous entity will be honored at the in-network benefit level. After this 90-day period, members must either transition to an in-network provider or utilize out-of-network benefits.

For self-insured plans, the TOC period may be customized based on plan preferences. For services or prescriptions with in-network providers, PAs will need to be renewed upon expiration.

Aetna has reported to Segal that their average denial rate for medical necessity is approximately 15%. However, there is limited publicly available data to make a direct comparison between carrier denial rates for commercial employer-sponsored health plans, such as those from BCBS NC and Aetna. While BCBS NC states on its website that 90% of claims are approved, a Kaiser Family Foundation study on non-group qualified health plans reported a denial rate of 13.7% for BCBS NC.²⁰ Various factors influence the denial rates of insurance carriers such as type of plan; employer-sponsored vs. Medicare advantage vs. non-group qualified plans making it difficult to determine if one carrier denial rate is better or worse than another.

Research and reporting on PA

Several organizations have collaborated and produced research, reports and recommendations on PA and UM:

Governmental and regulatory agencies

- Centers for Medicare & Medicaid Services (CMS)
- National Association of Insurance Commissioners (NAIC)

²⁰ J. Lo and R. Wallace, "Claims Denials and Appeals in ACA Marketplace Plans in 2021," KFF.org. 18 September 2024. <https://www.kff.org/private-insurance/issue-brief/claims-denials-and-appeals-in-aca-marketplace-plans/>.

Professional and advocacy organizations

- American Medical Association (AMA)
- America's Health Insurance Plans (AHIP)

Policy and economic research centers

- Kaiser Family Foundation (KFF)
- Segal, Milliman

Academic and research institutions

- Harvard University
- USC Schaeffer Center

These organizations, as well as many others conduct research and analyses and collaborate to assess the potential cost savings, operational efficiency, burden to physicians and impact to patients, collectively shaping the conversation around PA and informing policy.

Michigan-mandated PA reports

In April 2022, Michigan mandated that PAs be reported by insurers to the Michigan Department of Insurance and Financial Services. The law is known as Public Act 60 of 2022. The 2023 report containing 2022 data covers the following:²¹

- The number of PA requests:
 - Medical: 1,047,439
 - Pharmacy: 258,587
- The number of PA requests denied:
 - Medical: 76,250 (7.3% of medical PA requests)
 - Pharmacy: 94,653 (36.6% of pharmacy PA requests)
- The number of appeals received:
 - Medical: 6,603 (8.7% of medical PA request denials)
 - Pharmacy: 6,395 (6.8% of pharmacy PA request denials)
- The number of adverse determinations reversed on appeal:
 - Medical: 3,128 (47.4% of medical PA request denials)
 - Pharmacy: 3,028 (47.3% of pharmacy PA request denials)
- Of the total number of PA requests, the number of PA requests that were not submitted electronically.
 - Medical: 176,514 (16.9% of medical PA requests)
 - Pharmacy: 98,348 (38.0% of pharmacy PA requests)

²¹ [State of Michigan Department of Insurance and Financial Services, "Public Act 60 of 2022: SECTION 2212e (MCL 500.2212.e) Report: 2023," Lansing, 2023.

- The top 10 services that were denied:
 - Medical:
 - Inpatient hospital admission — 6.5% of denied medical requests
 - Outpatient physical therapy — 6.4% of denied medical requests
 - MRI: Lower spinal canal — 3.5% of denied medical requests
 - MRI: Leg joint — 3.0% of denied medical requests
 - Sleep monitoring of patient (6 years or older) in a sleep lab — 2.2% of denied medical requests
 - CT: Chest — 2.2% of denied medical requests
 - MRI: Any joint of upper extremity — 2.0% of denied medical requests
 - MRI: Cervical spine — 1.6% of denied medical requests
 - CT: Abdomen and pelvis — 1.2% of denied medical requests
 - Treatment of speech, language, voice, communication, and/or auditory processing disorder — 1.0% of denied medical requests
 - Pharmacy:
 - Ozempic — 4.9% of denied pharmacy requests
 - Saxenda — 3.3% of denied pharmacy requests
 - Nurtec ODT — 2.9% of denied pharmacy requests
 - Trulicity — 2.4% of denied pharmacy requests
 - Mounjaro — 2.0% of denied pharmacy requests
 - Wegovy — 2.0% of denied pharmacy requests
 - Ubrelyv — 1.2% of denied pharmacy requests
 - Vyvanse — 0.9% of denied pharmacy requests
 - Xifaxan — 0.8% of denied pharmacy requests
 - Dupixent — 0.7% of denied pharmacy requests
- The top 10 reasons PA requests were denied:
 - Medical
 - Medical necessity — 87.7% of denied medical requests
 - Contractual benefit exclusion or limitation (including site of care restrictions) — 6.3% of denied medical requests
 - Network limitations — 4.0% of denied medical requests
 - Lack of appropriate referral or timely notification — 0.7% of denied medical requests
 - Administrative denials — 0.5% of denied medical requests
 - Lack of clinical or supporting documentation — 0.3% of denied medical requests
 - Step therapy requirements not met — 0.3% of denied medical requests
 - Retrospective authorization denials — 0.2% of denied medical requests
 - Experimental/investigational — 0.2% of denied medical requests
 - Coordination of benefits — 0.01% of denied medical requests

- Pharmacy
 - Medical necessity — 33.8% of denied pharmacy requests
 - PA denial — 22.0% of denied pharmacy requests
 - Formulary or tiering restrictions — 14.1% of denied pharmacy requests
 - Step therapy requirements not met — 7.2%
 - Contractual benefit exclusions or limitations — 6.7%
 - Quantity limitations — 3.0%
 - Lack of clinical or supporting documentation — 1.8%
 - Not a prescription drug benefit — 0.4%
 - Administrative denials — 0.2%
 - Experimental/investigational 0.1%

The data represents approximately 8.5 million plan participants who are covered by either commercial health insurance, Medicaid, or Medicare Advantage. The data highlights a disconnect between provider recommendations and health plan medical and pharmacy policies. Additionally, the data for the medical and pharmacy PA reveal the differences between the function of PA for medical policy vs. pharmacy policy in practice. Only 7.3% of medical PAs were denied, and only 8.7% of those medical denials were appealed. However, the 47.4% reversal rate of appealed denials does indicate that there potentially administrative complexities and inefficiencies in the PA process that need to be addressed.

While 36.6% of pharmacy PAs were denied, what is clear is that PA is acting in many situations to enforce the other aspects of UM, such as tiering, quantity limits, and step therapy; 24.3% of denials are because of enforcing these other UM processes. At least 33.8% of pharmacy denials are due to a lack of medical necessity, which along with the medical denials highlights a disconnect between provider recommendations and health plan pharmacy policies. 22% of the denials were reported but not fully classified by their reporting insurer, and 14.6% of pharmacy denials are attributable to drugs traditionally used for diabetes but have recently been used for weight loss causing a large administrative burden for providers and insurers as they manage the demand for these medications for weight loss.

Medicare also provides insight into their PA data. For 2022, 46 million PA were submitted, 7.4% of requests were denied, and 9.9% of denials were appealed. Of the appealed denials, 83.2% of denials were reversed. These denial rates and appeal rates align with the Michigan data. The Medicare denial reversal rate is much higher, suggesting Medicare is either more lenient or simpler process compared to Michigan for appeals.²²

²² J. F. Biniek, N. Sroczynski and T. Neuman, KFF.org, 17 September 2024. <https://www.kff.org/medicare/issue-brief/use-of-prior-authorization-in-medicare-advantage-exceeded-46-million-requests-in-2022/>

What have other states done?

The ACA Marketplace compiles claims and denial data annually that is made available on Healthcare.gov. Data is available through plan year 2021.²³ The data reveals that, nationally, approximately 17% of in-network claims are denied in the individual marketplace plans representing approximately 5.7 million plan participants; 8% of denials can be attributed to PA while 14% of denials are attributable to excluded services. BCBS NC provides their data on approximately 180,000 enrollees in their ACA marketplace health plans. It is notable that BCBS NC has a 13.6% denial rate; 5.2% representing denied PAs, and 22% related to excluded services.²⁴ It is important to note that not all denials are as a result of PA.

44 states (including Washington, DC) have implemented a form of a PA mandate or regulation that either requires ePA processes and standards, or sets limits to response times for making a determination.²⁵ 31 states have mandated the use of electronic PA systems, and only seven with regulations states allow greater than five calendar days to process a non-urgent PA. Nine states do not currently have a state law mandating response times for PAs. No states limit or restrict PA regarding what type of treatment or medication it may apply to; regulations and mandates are focused on improving process efficiency, ensuring physicians are included in the PA process, and reducing the time it takes for insurers and health plans to make a determination.

While self-funded state health plans have flexibility in how they operate regarding PA, they typically abide by ERISA and/or their state's regulations. Just in 2024 alone, 10 states, including Vermont, Minnesota, Wyoming, Colorado, Illinois, Mississippi, Maine, Maryland, Oklahoma, and Virginia, have passed legislation aimed at PA; their legislative efforts align with trends to minimize delays and increase data transparency. Transparency is a key goal, with pushes to increase the publicly available reported data, including which procedures and medications are being impacted.²⁶

PA: health plan and provider costs

Third party administrators (TPAs) are utilized to manage claims administration and provide their expertise in designing and administering medical and pharmacy policy. The expectation is that utilization will be monitored, and clinically appropriate evidence-based care is provided by the contracted providers contracted to serve the network created by these TPAs. BCBS NC, Aetna, UnitedHealthcare, Cigna and Humana are examples of insurers who also provide TPA services such as network leasing, claims administration, medical and pharmacy policy guidance and UM.

²³ J. Lo and R. Wallace, "Claims Denials and Appeals in ACA Marketplace Plans in 2021," 18 September 2024. <https://www.kff.org/private-insurance/issue-brief/claims-denials-and-appeals-in-aca-marketplace-plans/>

²⁴ Center for Consumer Information and Insurance Oversight, "Transparency in Coverage PUF - PY2024," 18 September 2024. <https://data.healthcare.gov/dataset/5c232812-fc30-4dd7-8af7-015ce0073eb8>

²⁵ American Medical Association, "2024 Prior Authorization State Law Chart," American Medical Association, 2024.

²⁶ T. A. Henry, "10 states have tackled prior authorization so far in 2024," American Medical Association, 19 August 2024. <https://www.ama-assn.org/practice-management/prior-authorization/10-states-have-tackled-prior-authorization-so-far-2024>. [Accessed 25 September 2024].

The criticism levied against TPAs is that they put plan cost ahead of patient care. There are instances where delays in care due to UM have caused unintended results. However, the evidence suggests that PA results in cost savings for health plans. The Centers for Medicare and Medicaid intends to transition to a fully electronic submission system for PA and make the PA process more transparent.²⁷ Reducing the administrative burden on providers could result in lower overall healthcare costs if providers choose to reduce their costs accordingly. Physicians and their staff spend on average 12 hours per week completing PAs.²⁸ Time per PA is reported as 11-16 minutes for ePA processes and up to 24 minutes for manual claim status inquiries. Manual PA cost providers on average \$10.97 per event while ePA reduces the cost to a range of \$5.84-\$9.08 per event.²⁹ PAs that are complex and require multiple levels of appeals that can cost significantly more. A reasonable range per PA would fall between \$10-\$50 per PA. In contrast, health plans and insurers are spending in the range of \$0.05 (ePA) to \$3.52 (manual) per PA.²⁹

The Massachusetts Association of Health Plans (MAHP) commissioned a report to evaluate the impact of eliminating PA. PA and UM more broadly serve the purpose of both managing medical and pharmacy policy, but also in managing behavior. Moral hazard occurs when patients or providers utilize more healthcare services than necessary because they are insulated from the direct costs, leading to overutilization. Volume-based provider reimbursement models and over-insuring patients can lead to patients seeking excessive treatments and providers offering more services than are clinically necessary.

The sentinel effect describes how the presence of oversight or the potential for review influences behavior. Knowing that decisions are subject to review, providers are more likely to adhere to evidence-based guidelines, reducing unnecessary care, and pursuing PA when necessary.

UM and PA specifically mitigates moral hazard and enhances adherence to clinical standards through the sentinel effect. Precise care and caution are required when analyzing and modifying UM strategies within the medical and pharmacy policy.³⁰ Removing PA may streamline aspects of care and reduce administrative burden. It would also weaken cost controls and oversight, increasing the potential for overutilization, unnecessary or low-value care, and higher healthcare costs.³¹

The MAHP commissioned report found that removing PA would result in an increase in premiums in a range from 5.1% to 23.3%, dependent upon the percentage increase in submitted claims due increased costs and utilization due to lack of oversight and protection granted by the sentinel effect.³¹ PA was found to mitigate 9.9% to 10.5% of paid expenses subject to the PA process. On a conservative assessment, if 10% of claims are subject to PA, and 10% of those costs are mitigated by PA, then 1% of additional total claims costs for an insurer or health plan are mitigated by PA while the participant is directed to a clinically

²⁷ M. A. Kyle and Z. Song, "The Consequences and Future of Prior-Authorization Reform," *New England Journal of Medicine*, pp. 291–293, 2023.

²⁸ American Medical Association, "2023 AMA prior authorization physician survey," American Medical Association, Chicago, 2024.

²⁹ CAQH, "2023 CAQH Index Report," CAQH, Washington, D.C., 2024.

³⁰ F. S. Busch and P. Fielek, "Potential Impacts on Costs and Premiums Related to the Elimination of Prior Authorization Requirements in Massachusetts," Milliman, Brookfield, 2023.

³¹ Z. Brot-Goldberg, S. Burn, T. Layton and B. Vabson, "Rationing Medicine Through Bureaucracy: Authorization Restrictions in Medicare," University of Chicago Becker Friedman Institute, Chicago, 2023.

appropriate alternative solution. PA actively works to both reduce existing unavoidable claims expense, while also working to mitigate inefficient and unnecessary expenses before they occur.

Provider and patient impact of PA

Health plans and Insurers demonstrably save costs utilizing PA while providers and patients bear a burden for this cost savings. There is insufficient data available to draw firm conclusions regarding the impact to health outcomes universally due to PA or other UM processes. However, there are specific areas of care that do show impacts, such as delays or declined care opportunities due to PA.

Provider experience

In addition to the cost associated with administering the PA process, providers when surveyed convey additional concerns with the process. According to the American Medical Association, 94% of providers report that their patients experience delays in treatment, while 78% of providers report that this may lead to abandonment of the suggested treatment. 93% of providers experience PA as having a negative impact and 35% of providers report that the PA criteria are rarely or never evidence based. Notably, 24% of providers have reported that a PA has resulted in serious adverse health impacts to their patients.³²

Oncology is a practice area impacted by PA due to the high cost of emerging medications and treatments. A study from the American Society of Clinical Oncology found that treatment discontinuation and new prescription access delays. If PA was added to an existing treatment or medication, approximately 7% of patients were found to discontinue that treatment within 120 days. 8% to 11% of patients experience delays longer than 10 days to access medications after a PA requirement was newly required or for a first refill.³³

Sometimes the PA process can delay the treatment of care potentially up to 10 months if an external appeal is required in a non-urgent scenario. A potentially vulnerable population experiencing delays, difficulties and confusion around any UM process does result in abandonment of recommended treatment. However, the results are mixed and not universally applicable across fields of medicine. Behavioral health studies found both positive and negative results; PA for antipsychotic drugs for schizophrenia positively correlated to fewer emergency department admissions and lower drug costs for the population studied in a Georgia Medicaid program, while a similar study in Maine found a significant increase in risk of treatment abandonment.³⁴

The interaction of PA with other aspects of benefit design lacks sufficient specific study. Studies have shown mixed results, with some showing that higher cost sharing is more effective than PA in reducing adverse risk associated with a treatment protocol, but there are also studies that find the opposite to be true.³⁵

³² American Medical Association, "2023 AMA prior authorization physician survey," American Medical Association, Chicago, 2024.

³³ A. Kyle, PhD, RN and N. L. Keating, MD, MPH, "Prior Authorization and Association with Delayed or Discontinued Prescription Fills," *Journal of Clinical Oncology*, pp. 951-960, 2023.

³⁴ A. Turner, G. Miller and S. Clark, "Impacts of Prior Authorization on Health Care Costs and Quality," The National Institute for Health Care Reform, Auburn Hills, 2019.

³⁵ California Health Benefits Review Program, "Analysis: Prior Authorization in California," California Health Benefits Review Program, Berkeley, 2023.

PA impact summary

Survey results are inconclusive and conflicting — depending on who you ask — providers vs. health plan professionals. However, it appears that the patient experience is largely not impacted by PA, because treatment may progress using more appropriate clinical alternatives. The healthcare provider experience is generally negative in that there is a clearly demonstrated disconnect between health plan or insurer processes and provider expectations.

PA Survey and Research Summary

Research/Survey Category	Positive	Mixed Views	Negative
Patient safety	X		
Access to healthcare services		X	
Utilization of healthcare services subject to PA		X	
Utilization of other healthcare services		X	
Health outcomes		X	
Reducing excess spending, including waste & fraud	X		
Patient experience		X	
Provider experience			X

Impact summary

PA works effectively to curtail fraud, waste, and abuse. Health plans and insurers save money by having UM programs including PA. It is not a perfect process, and while progress has been made toward reducing processing times and the administrative burden on all participants in the process there are still obstacles that need to be overcome. PA overall contributes positively to patient safety and does not universally negatively impact access to healthcare services. Healthcare services can be impacted by implementing PA, but alternative clinically appropriate treatments are available and recommended.

While PA can demonstrably result in delays in access to medications when newly implemented as a process, or result in treatment abandonment, survey results are inconclusive and conflicting regarding the universal impact on health outcomes. The patient experience is largely not impacted by PA, as treatment may not progress as the provider recommends, but alternatives are provided with appropriate clinical efficacy. Understandably, provider experience is negative; There is a clearly demonstrated disconnect between insurer/health plan processes and provider expectations. While PA may occur on 9-14% of all claims, only approximately 10% of denials are appealed. Appeals do result in a high reversal rate (50% or in some instances over 80%), but this does not indicate a universal process failure. The removal of PA would result in increased rate of low-value care being administered and patient safety being compromised. Providers are invaluable to the process and their input is useful and necessary to arrive at recommendations that drive appropriate improvements.

Best practices and recommendations

Patient safety and health plan sustainability are key components when evaluating recommendations for the SHP. While providers are universally impacted and burdened with the PA process, patients are not equally burdened or universally impacted. Most plan participants utilizing the health plan's resources will not engage or be impacted by PA directly; Indirectly, it may still influence their provider's course of treatment if they are aware that their potential treatment plans could trigger the PA process.

Removing PA is not recommended. However, federal agencies, state governments, provider advocacy groups, health plans and insurers all agree that it can and should function more efficiently and with greater transparency.* Recommendations and best practices are going to focus on increasing transparency on clinical guidelines, health plan utilization and administrative process efficiency.

The SHP currently has a Pharmacy & Therapeutic Committee whose purpose is to review and evaluate pharmacy policy, including UM; "pursuant to N.C.G.S. §§ 135-48.51(2) and 58-3-221(a)(1) the North Carolina State Health Plan (Plan), by maintaining a closed formulary, must develop the formulary and any restrictions on access to covered prescription drugs or devices in consultation with and with the approval of a pharmacy and therapeutics committee, which shall include participating physicians who are licensed to practice medicine in North Carolina."³⁶ Clinical guidelines are set by medical policy committees and pharmacy and therapeutics committees.

CVS Caremark, Aetna, and BCBS NC all publish their policies including their explanation for the development of their medical and/or pharmacy & therapeutic guidelines^{37, 38, 39} California passed Senate Bill 855 in 2020 which prohibits commercial insurers to use policies developed internally and must reference nonprofit associations such as the Institute for Clinical and Economic Review (ICER), the National Comprehensive Cancer Network (NCCN), the American College of Cardiology (ACC), and the U.S. Preventive Services Task Force (USPSTF) when updating or creating policy guidelines.⁴⁰ Since 2020, insurers who operate in California, such as Aetna, Blue Cross Blue Shield Association, UnitedHealthcare, CVS, and Kaiser manage their Medical and Pharmacy policies in line with California's requirements.

The cost of creating an internal medical policy committee is costly as well. It would require a combination of full time and contract physicians to convene as often as quarterly to review the existing SHP medical policies. Each medical field, such as cardiology and oncology, would require a medical and policy expert to advise and provide field specific expertise. The ICER for example has an annual operating budget of approximately \$6 million; two-thirds of which is

* K. Pestaina and K. Pollitz, "Examining Prior Authorization in Health Insurance," 23 September 2024. <https://www.kff.org/policy-watch/examining-prior-authorization-in-health-insurance/>.

³⁶ North Carolina State Health Plan, "North Carolina State Health Plan Pharmacy and Therapeutics (P&T) Committee Charter," 23 September 2024. <https://www.shpnc.org/pharmacy-and-therapeutics>.

³⁷ CVS Caremark, "Information for health care professionals," 23 September 2024. <https://www.caremark.com/pharmacists-medical-professionals.html>.

³⁸ Blue Cross and Blue Shield of North Carolina, "Policies, guidelines and codes," 23 September 2024. <https://www.bluecrossnc.com/providers/policies-guidelines-codes>.

³⁹ Aetna Inc, "Clinical policy bulletins," 23 September 2024.: <https://www.aetna.com/health-care-professionals/clinical-policy-bulletins.html>.

⁴⁰ K. Pestaina and K. Pollitz, "Examining Prior Authorization in Health Insurance," 23 September 2024. <https://www.kff.org/policy-watch/examining-prior-authorization-in-health-insurance/>.

spent on salaries and compensation.⁴¹ The recommended best practice would be to annually review the clinical guidelines and policies that based on plan utilization trigger PA and ask the health plan administrator for recommendations to reduce provider burden without unnecessarily compromising patient safety or cost.

Requesting complete UM and PA reporting is a recommended best practice. Quarterly reviews of health plan utilization are common, and while special programs or overall savings or cost avoidance may be highlighted, request clinically specific and detailed reporting. This enhances transparency in the UM process and can highlight areas in the plan that PA might be safe to relax or eliminate.

Additionally, the AMA has model legislation that recommends the following regarding PA:⁴²

- Reduce the health plans' time to respond to PA requests
- Qualified physician is making the determination if it is a denial
- Require health plans and insurers to post PA statistics publicly and submit them to state insurance departments
- Prohibiting retroactive denials when care is preauthorized; unless materially misrepresented
- PAs remain valid for at least one year even if a dose changes
- PA remain valid for the length of treatment for chronic conditions
- Require new health plans or administrators to honor existing PAs for at least 90 days

The SHP already requires above standard response times; three business days for non-urgent PA requests and 72 hours for urgent requests. Denials are typically made by consensus with a Medical Director, who is typically a physician, as part of the process. While the SHP already adheres to two of these seven AMA recommendations, it is suggested to confirm any existing deviations in the policy or practice associated with PA or associated UM processes directly with Aetna.

Reported data should be anonymized to remain in compliance with HIPAA. During the PA process it is common for health plan representatives to be made aware of PA requests that are denied to review and potentially allow the treatment or procedure to proceed despite the recommended denial. This shared data should still be anonymous and in compliance with HIPAA policy and procedures. Notably, once a health plan decides to reverse a denial, then all similar cases moving forward must also be approved; this would apply to medications as well if a denial was reversed by a health plan.

It is recommended to review denials and utilization as frequent as quarterly based on de-identified and aggregated data to make broad based changes such as lifting PA requirements on drugs and services in which the majority of requests are approved and continue to monitor these augmentations to ensure they remain appropriate.⁴³ Any data made available to the board

⁴¹ Institute for Clinical and Economic Review, "Sources of Funding," 23 September 2024. [Online]. Available: <https://icer.org/who-we-are/independent-funding/sources-of-funding/>.

⁴² T. A. Henry, "9 states pass bills to fix prior authorization," 23 September 2024. [Online]. Available: <https://www.ama-assn.org/practice-management/prior-authorization/9-states-pass-bills-fix-prior-authorization>.

⁴³ [A. Turner, G. Miller and S. Clark, "Impacts of Prior Authorization on Health Care Costs And Quality," The National Institute for Health Care Reform, Auburn Hills, 2019.

of trustees or also publicly should be de-identified, anonymized, and aggregated and in compliance with HIPAA.

Providers are contractually obligated to meet minimum standards of care and maintain positive health outcomes. Health plans and insurers do not additionally incentivize providers through metrics such as number of PAs completed. Some programs exist to reward providers with fewer administrative burdens, or by placing them into a preferred provider category. While it may be appropriate to highlight efficient providers who have higher rates of positive health outcomes, direct and additional compensation is not a recommended practice.

Exclusion programs, sometimes referred to as gold carding, first introduced in Texas, enables physicians with high rates of PA approvals and who also meets higher-than-average clinical standards be exempt from PA requirements. The UnitedHealthcare Gold Card Program recognizes qualified practices that have consistently demonstrated adherence to evidence-based guidelines, regardless of which state.

North Carolina State Health Plan obligations

The SHP is not subject to most federal mandates, such as ERISA, and not subject to all state mandates as a sovereign immunity as a government entity. The health plan is subject only to internal oversight and internal state regulations or laws as they relate to public employees and/or their benefits, such as N.C.G.S. §§ 135-48.51 and 58-3-221 requiring the formation of the P&T Committee. Additionally, the state health plan is subject to certain Affordable Care Act mandates such as preventive care, comprehensive coverage requirements, and the prohibition on pre-existing conditions. Nondiscrimination provisions like the Civil Rights Act or the Americans with Disabilities Act also apply to the state health plan. The North Carolina Department of Insurance specifically does not regulate the state health plan.⁴⁴ Specific to PA or UM, unless required in collective bargaining agreements there are no laws or mandates that the SHP are obligated to follow.

Conclusion

The SHP actively participates in UM, including the requirement of PAs for specific services. The SHP is switching networks and administrators on January 1, 2025, from BCBS NC to Aetna. The change in administrator and network will result in slight changes to their existing UM processes. Aetna has 40% fewer CPT codes subject to PA than BCBS NC. The cost mitigation associated with PA greatly outweighs the administrative burden to providers. Additionally, since 2017 the P&T Committee has been meeting regularly to review the pharmacy closed formulary including the UM policies associated with individual medications. CVS Caremark is remaining as the pharmacy benefit manager. UM is a regular agenda item for the P&T Committee.

The SHP's PA timeline for determination at three business days for non-urgent PAs and 72 hours meets exceeds federal or state level mandates. The process is clearly outlined, with a formal transparent appeals process. Recommended best practices will focus on greater transparency, thorough reporting and process efficacy.

⁴⁴ "Health Plans We Do Not Regulate," NC Department of Insurance, 23 September 2024. <https://www.ncdoi.gov/consumers/health-insurance/health-plans-we-do-not-regulate>.

Recommendations:

- Request full de-identified, aggregated reporting on prior utilization determinations
 - Request and review individual service area metrics for greatest impact of denials
 - Request and review individual service area metrics to be able to evaluate relaxing PA based on consistent approvals
 - Review time for determinations
 - Review appeals, length of appeals
 - If possible, track denials that result in approvals for the same CPT code within 12 months
- Prohibiting retroactive denials when care is preauthorized; unless materially misrepresented
- PAs remain valid for at least one year even if a dose changes
- PA remain valid for the length of treatment for chronic conditions
- Require new health plans or administrators to honor existing PAs for at least 90 days
- Remove \$500 penalty for failure to receive PA
- Consider removing PA for home-based services and inpatient hospice. Aetna does not require PA for these services.
- Consider removing PA for in-network dialysis
- Together with Aetna, consider a gold card approach similar to other carriers for qualified practices that have consistently demonstrated adherence to evidence-based guidelines.

These recommendations will enable ongoing evidence-based review and potential modification of the PA process, while enabling a smooth transition from BCBS NC to Aetna in 2025. Standardizing validation periods will make it easier to providers to manage treatment protocols and reduce the disconnect between providers and the health plan's PA policy. Alleviating provider burden and improving sentiment is a high priority in ensuring consistent and quality participant care. PA reduces plan costs and increases patient safety.

Appendix

UM can broadly be broken into six categories:

- Pre-service authorization & coverage approval
 - PA
 - Pre-certification
 - Medical necessity review
- In-service monitoring & care management
 - Concurrent review
 - Case management
 - Discharge planning
- Post-service evaluation & review
 - Retrospective review
 - Appeals process
- Pharmacy & treatment optimization
 - Step therapy
 - Formulary management
 - Quantity limits
- Provider & network management
 - Provider credentialing
- Patient safety & risk assessment
 - Health risk assessments

PA operates within the broader operational context of utilization management to enforce compliance, reduce unnecessary treatments, and promote efficient resource use. PA predominantly applies to the following healthcare services:

- Surgeries and procedures
 - Elective surgeries
 - Transplants
 - Cosmetic or reconstructive surgeries
- Advanced diagnostic imaging
 - MRI, CT, PET scans
 - Nuclear medicine studies
- Hospital and facility admissions
 - Inpatient hospital admissions
 - Skilled nursing facility stays
 - Rehabilitation and long-term care admissions
- Pharmacy and medications
 - Specialty medications

- High-cost medications
- Drugs with quantity limits or step therapy requirements
- Behavioral health and substance abuse
 - Inpatient mental health and substance use treatment
 - Partial hospitalization and outpatient programs
- Home health services
 - Home nursing and infusion therapy
 - Rehabilitation therapies at home (physical, occupational, speech)
- Durable medical equipment
 - Mobility aids (wheelchairs, prosthetics)
 - CPAP machines, oxygen equipment
- Specialty treatments and procedures
 - Fertility treatments (e.g., IVF)
 - Gene and cellular therapies (e.g., CAR-T, stem cell transplants)