

AMERICAN ASSOCIATION OF
NEUROLOGICAL SURGEONS

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American
Association of
Neurological
Surgeons



Congress of
Neurological
Surgeons

CONGRESS OF
NEUROLOGICAL SURGEONS

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August 12, 2019

Seema Verma, MPH, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-6082-NC
PO Box 8016
Baltimore, MD 21244-8016

SUBJECT: Reducing Administrative Burden to Put Patients Over Paperwork

Dear Administrator Verma,

On behalf of the American Association of Neurological Surgeons (AANS) and the Congress of Neurological Surgeons (CNS), representing more than 4,000 practicing neurosurgeons in the U.S., we appreciate the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) ongoing Patients over Paperwork initiative. Like you, we believe that reducing unnecessary administrative burden is critical to lowering costs and removing obstacles that get in the way of physicians delivering high-quality care to their patients. While our health care system, including the Medicare and Medicaid programs, is complex, over time, the accumulated regulatory burdens foisted on physician practices has reached a tipping point.

Our comments will focus on the single most pressing issue facing neurosurgical practices today: burdensome utilization review programs — including prior authorization and appropriate use criteria (AUC) for advanced diagnostic imaging.

PRIOR AUTHORIZATION

Framing the Issue

Prior authorization is a cumbersome process that requires physicians to obtain pre-approval for medical treatments or tests before rendering care to their patients. The process for obtaining this approval is burdensome and costly to physician practices, requiring physicians and their staff to spend an enormous amount of time each week negotiating with insurance companies. As a result, patients are now experiencing significant barriers to medically necessary care, even for treatments and tests that are eventually routinely approved.

A recent survey¹ of neurosurgeons conducted by the AANS and the CNS found the following:

Prior Authorization Burden in Neurosurgical Practice has Increased

- Ninety-one percent of neurosurgeons report that the **burden** associated with prior authorization has **significantly increased** over the past five years.
- Insurers have **increased** the use of **prior authorization** over the past years for procedures (95%); for diagnostic tools (93%); and for prescription medications (55%).

¹ See Attachment 1.

- In any given week, many neurosurgeons (41%) must contend with between 11 and 40 prior authorizations. More than one-quarter (27%) of respondents face **more than 40 per week**.
- Many neurosurgeons must now engage in the so-called **peer-to-peer** process to obtain prior authorization, and nearly one-third (32%) of respondents experience this requirement for 26% to 75% or more of their services (including prescription drugs, diagnostic tests and medical services).
- More than three-fifths (62%) of neurosurgeons have staff members **working exclusively** on prior authorization, with most staff spending between 10-20 hours per week on prior authorization.
- **Ultimately**, the **majority of services** are **approved** (80%), with nearly forty percent (39%) of neurosurgeons getting approved 90% or more of the time.
- Unbelievably, **despite gaining prior authorization**, insurance companies **deny payment** after services are rendered, an outcome three-fifths of neurosurgeons have experienced more than once in the past year, and 24% have had this happen 20 or more times.

Patient Access to Care is Impacted

- Eighty-two percent of respondents state that prior authorization either always (34%) or often (49%) **delays access** to necessary care.
- The **wait time** for prior authorization can be **lengthy**. For most neurosurgeons (67%) it takes between 2 to 14 days to obtain prior authorization, but for 22%, this process can take from 15 to more than 31 days.
- Prior authorization causes patients to **abandon treatment** altogether with 21% reporting that patients often abandon treatment and 60% reporting that patients sometimes abandon treatment.
- Overwhelmingly (88%), neurosurgeons report that prior authorization has a significant (37%) or somewhat (51%) **negative impact** on patient **clinical outcomes**.

Observations from Practicing Neurosurgeons

The comments from our members are particularly illustrative regarding the burden of prior authorization on their practices, with one neurosurgeon summing-up the prior authorization process in a single word — “**exhausting**.” Some observations include:

“**Peer to peer** level discussions are frequently unnecessary and unnecessarily delay surgical intervention. The clinicians that we speak to are not specialty-specific, and many times have no idea what the procedure we are proposing even is.”

“**Peer to peer** is not a reality. Those phone calls rarely have a physician with my same specialty, and on spine cases, the individual is not neurosurgeon or even an orthopaedic spine surgeon. Some are reading a protocol (script) that they have been given to justify **delaying or canceling patient access** to care.”

“I spend an absurd amount of time dealing with prior auths and **peer to peers**, which is time I need to have dedicated to my patient care. The process is obnoxiously inefficient for health care providers. It is unrealistic to think that a health care provider can give an exact date and time to be able to be reached to discuss the reason a patient needs an image that is for surgery. Our day is unpredictable. I shouldn't have to spend 20-50 minutes on the phone explaining the reasons behind diagnostics only to be told that a physician will need to make the final decision and that the appointment needs to be scheduled for a different date only to spend 20-40 minutes explaining myself over again. Something needs to change.”

“[ABC health plan] is by far the worst offender. They deny frequently and never read my chart notes, which are very thorough and contain all the information needed to get authorization. I still

have to speak to a non-peer physician, who never looks at the notes beforehand. It is a complete waste of time. I would consider this a top cause of **physician burnout** and makes me think about retirement on a daily basis!”

“The increasingly burdensome process of pre-auth has led to a significant increase in the **cost of running a practice** and **staff burnout**. There are increased cancellations of surgery and imaging that causes significant frustration to patients who plan time off from work as well as the loss of revenue for hospitals as valuable OR and MRI time slots are wasted on a weekly basis. This makes the delivery of high-quality pre-operative care very hard. Interestingly, almost all the requested neurosurgery procedures and imaging eventually get authorized, confirming that this process is meant to limit care but slowing down the process, rather than critically looking at the indications for each request.”

“It has been a significant **burden on the practice** and has resulted in many **delays in care**. These delays have resulted in patients suffering. Worse, patients have had to choose between urgent surgery that prevents further neurological deterioration but with the risk that it will ultimately be denied, versus waiting for approval, knowing that they may irreversibly deteriorate while they are waiting. This has significantly and adversely affected patient health and happiness.”

“I am in a university practice. I have no say in what insurance plans are accepted. With **100% of our appeals ultimately approved**, it is clear that this process has not helped a single patient under my care and only delays their care with an unnecessary process-delay loop. It has increased **patient dissatisfaction**, as well as **provider dissatisfaction**, frustration, and **burnout**. It is creating big problems in my ability to treat patients.”

“We have **1.5 staff** to take care of three surgeons’ prior authorizations, and then the surgeons end up spinning their wheels with **peer to peer**, which is never a true peer. Many of our patients just lose hope of getting the care that is recommended. It is a sham and a way for the insurance carriers to deny care. This has made the **practice of medicine almost unbearable**.”

“We have decided it’s just a game to try to **delay patients** in hopes that they will give up and not have the services recommended. ABC health plan will often not authorize an MRI scan until physical therapy is done, so we are treating the patient without knowing what is going on. Then when we try to get authorization for surgery, they often require the patients to have recent physical therapy and injections even if the imaging and exam clearly demonstrate the need for surgery. Most of the time, **peer review** is not with a neurosurgeon or even a spine doctor of any capacity. We’ve had podiatrists and pediatricians making decisions for spine and brain surgery.”

“The majority of the time prior authorization process **delays access** to surgery and rarely, if ever, actually changes the plan of care. Reform is needed.”

“With the exception of fee-for-service Medicare, prior authorization occurs now almost across the board. As a board-certified neurosurgeon, I cannot order an MRI scan of the spine without asking the patient to complete a course of physical therapy, whether or not I think it will be beneficial. If I attempt to order an MRI on a patient who has not had physical therapy, the patient will automatically receive a generic form letter, which ultimately **delays** diagnostic workup, care delivery, and mandates physical therapy. In most instances, if I feel the therapy will be of no benefit, it actually has no long-term effect or positive benefit and actually **increases their healthcare cost**. There is certainly a place for physical therapy, but that should be ordered as a result of my judgment rather than by the insurance company. Not only does this interfere with patient care, but in my opinion, constitutes *de facto* practice of medicine by the insurance company without a license. The entire process results in a higher number of office visits in order

to document what the insurance company perceives as justification for the MRI, untold man-hours of the office personnel and staff dealing with the authorization and a significant delay, frustration, and disappointment for the patients.”

As you can see, there is a great deal of frustration with a process that adds unnecessary administrative burden and costs to physician practices, delays medically necessary care and saves the health care system very little since most prior authorizations are ultimately approved (indeed, health care costs may actually increase because of delays or other unnecessary care — e.g., physical therapy or office visits before an MRI scan).

Solving the Problem

Turning to solutions, the AANS and the CNS believe that CMS can lead the way in addressing this problem by adopting some reasonable requirements for Medicare Advantage (MA) plans. Joining with more than 125 medical organizations, we have endorsed the “Prior Authorization and Utilization Management Reform Principles.”² Additionally, we fully support the “Consensus Statement on Improving the Prior Authorization Process,” agreed to by the American Hospital Association, America’s Health Insurance Plans, American Medical Association, American Pharmacists Association, Blue Cross Blue Shield Association and the Medical Group Management Association.³ The recommendations below are consistent with the Consensus Statement principles.

1. **Standardization and Automation.** Each MA plan may have different forms or formats for their prior authorization requests, proprietary portals. Remarkably, in the 21st Century, plans also still require physicians to use facsimile machines. CMS must accelerate the use of standard electronic prior authorization (ePA) to facilitate an automated process that is integrated into the physician practice’s electronic health record (EHR) system and workflow. Re-entering data into a health plan’s proprietary online portal, downloading forms from an insurance company website and faxes should not be treated as electronic transmissions. The benefits of ePA are clear in that it would establish a uniform process, eliminate the need to manage numerous payer portals and accelerate time to treatment. In adopting ePA, however, it is essential that this technology not add more burden and costs on physicians.

Ultimately, the ePA process and standards must allow for the efficient transfer of clinical information to facilitate automatic, real-time prior authorization decisions — particularly for items and services that are routinely approved.

2. **Reduce Prior Authorizations.** A consistent complaint about the current prior authorization process is that ultimately, a high percentage (90 percent or more) of medical services or tests are approved. CMS should, therefore, minimize the use of prior authorization for services that are routinely approved, focusing instead on those gray areas where the evidence is not as clear-cut, or a service is not covered. Moreover, CMS should prohibit additional prior authorization for medically-necessary services performed during a surgical or invasive procedure that already received, or did not initially require prior authorization.
3. **Transparency.** Increase transparency by requiring MA plans report to CMS annually the following:
 - a list of items and services that are subject to a prior authorization;
 - the percentage of prior authorization requests that are approved;

² See Attachment 2.

³ See Attachment 3.

- the average and median time for approval (in hours);
- the average and median amount of time (in hours) that elapsed between the submission of the prior authorization request and the MA plan determination; and
- the percentage of requests that were initially denied, appealed and subsequently overturned.

Either the MA plans or CMS should publish this information on public websites so patients and providers can assess these metrics when deciding whether to enroll or participate with a particular MA plan. Additionally, MA plans must make it clear what medical or other documentation is required for the plan to review and complete the prior authorization request.

4. **Accountability.** To hold MA plans accountable to patients, providers and the Medicare program, CMS should take the following steps:

- require plans to make timely prior authorization determinations, provide rationales for denials and ensure that any “peer-to-peer” reviews utilize physicians from the same specialty/subspecialty as the ordering or prescribing physician;
- maintain continuity of care for individuals transitioning to, or between, MA plans to minimize any disruption to ongoing treatment;
- conduct annual reviews of items and services for which prior authorization requirements are imposed by MA plans through a process that takes into account input from physicians and is based on current evidence-based medicine guidelines or clinical criteria; and
- prohibit MA plans from denying claims for services or procedures that have been approved following prior authorization.

Neurosurgeons take care of very sick patients who suffer from painful and life-threatening neurologic conditions such as brain tumors, debilitating degenerative spine disorders, stroke and Parkinson’s Disease. Without timely medical care, our patients often face permanent neurologic damage, and sometimes death. If CMS takes the above-outlined steps to streamline prior authorization, it will be a tremendous improvement. Physician burden will be significantly reduced, but more importantly, requiring MA plans to fix the broken prior authorization process will help ensure seniors’ timely access to the medically-necessary care they need when they need it.

AUC FOR ADVANCED DIAGNOSTIC IMAGING SERVICES

While the AANS and the CNS are committed to consulting with appropriate use criteria before ordering advanced diagnostic imaging tests, we continue to have deep concerns about Medicare’s AUC for Advanced Diagnostic Imaging Program. More than five years have passed since the enactment of the Protecting Medicare Access Act (PAMA), which established the AUC Program, and much has changed since 2014. In this regard, the Medicare AUC Program:

- **Is outdated.** The AUC Program is unnecessary in the environment of evolving payment and delivery models in which providers are at financial risk. Physicians are now incentivized through the Quality Payment Program (QPP) to improve health care quality and reduce resource use. Medicare requires alternative payment model (APM) participants to assume more downside risk. And CMS estimates that one in four primary care providers will participate in Medicare direct contracting models scheduled for 2020 implementation.
- **Diverts provider resources away from quality improvement.** The AUC Program implementation is occurring at the same time providers are struggling to assign adequate

resources for health information technology infrastructure and QPP participation. Additionally, the AUC Program has no metrics of quality or patient outcomes.

- **Adds administrative burden.** The number of clinicians affected by the program is vast, crossing almost every medical specialty, including primary care, and CMS estimates that 579,687 ordering professionals will be subject to this program. The AUC Program sets up a complex exchange of information between clinicians that is not yet supported by interoperable EHR systems and relies on claims-based reporting at the same time CMS is migrating away from claims reporting for quality data. The coding methods to include G-codes and modifiers to report the required AUC information on Medicare claims, and such a new reporting system introduces significant burden to physicians. Moreover, the AUC Program it is duplicative of the QPP, so physicians are going to be documenting and reporting on multiple programs, with little demonstrated value.
- **Is a costly and disproportionate response to imaging utilization.** According to the Medicare Payment Advisory Commission, imaging volume has dropped .2 percent on average each of the last five years (2012-2016) with advanced imaging accounting for only 4.7 percent of total Medicare allowed charges in 2017.⁴ By some estimates, it will cost physicians \$75,000 or more to implement the AUC program — again, in addition to investments that physicians are already making to participate in the QPP.
- **Takes away provider flexibility for consulting AUC.** Clinicians are required only to use Clinical Decision Support Mechanisms qualified by CMS, which, in many cases, will force clinicians to abandon long-standing methods of AUC consultation, as well as the consultation of specialty-specific AUC. By CMS' admission, information on the benefits of physicians adopting qualified CDSMs or automating billing practices for specifically meeting the AUC requirements do not yet exist, and "information on benefits overall is limited."⁵

Since there remain many outstanding technical and practice workflow questions and challenges, the AANS and CNS appreciate that the July 26, 2019, CMS transmittal to the Medicare Administrative Contractors (MACs) updating information about the AUC Program states that CMS will continue to pay claims that do not include the consultation information or that contain errors related to the AUC information. **We strongly recommend that CMS continue to delay the full implementation of this program** until these complex implementation issues are fully resolved.

Ultimately, the AANS and the CNS firmly believe that the AUC Program must be harmonized with the QPP, incorporating the consultation of AUC into the quality program, rather than perpetuating a stand-alone program that includes no measures of quality or patient outcomes. We do appreciate that CMS has made clear that the agency lacks the administrative authority to make any substantial changes to the program, but we believe that delaying full implementation will allow stakeholders to work with Congress to pass legislation that will provide CMS with the flexibility to incorporate AUC more broadly into the QPP.

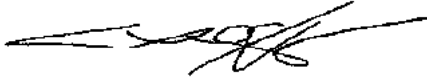
Finally, the American Medical Association has provided extensive comments and recommendations regarding the AUC Program in its comment letter in response to this RFI, and the AANS and the CNS support the AMA's views.

⁴ Medicare Payment Advisory Commission Report to the Congress: Medicare Payment Policy, March 2019; http://www.medpac.gov/docs/default-source/reports/mar19_medpac_entirereport_sec.pdf?sfvrsn=0 (accessed August 2019).

⁵ Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule and Other Revisions to Part B for CY 2019.

The AANS and the CNS appreciate your commitment to putting patients over paperwork to remove unnecessary burdens on physicians and their practices, and urge you to rethink the entire prior authorization process and AUC for advanced diagnostic imaging programs for the betterment of our patients. We thank you for considering our comments and recommendations, and if you have any questions or need additional information, please do not hesitate to contact us.

Sincerely,



Christopher I. Shaffrey, President
American Association of Neurological Surgeons



Ganesh Rao, MD, President
Congress of Neurological Surgeons

Enclosures

Contact

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ATTACHMENT 1: AANS/CNS Prior Authorization Survey Results



PRIOR AUTHORIZATION SURVEY

TOP-LINE RESULTS

Patient Access to Care Has Been Impacted

- Eighty-two percent of respondents state that prior authorization either always (34%) or often (49%) **delays access** to necessary care.
- The **wait time** for prior authorization can be lengthy. For most neurosurgeons (67%) it takes between 2 to 14 days to obtain prior authorization, but for 22%, this process can take from 15 to more than 31 days.
- Prior authorization causes patients to **abandon treatment** altogether with 21% reporting that patients often abandon treatment and 60% reporting that patients sometimes abandon treatment.
- Overwhelmingly (88%), neurosurgeons report that prior authorization has a significant (37%) or somewhat (51%) **negative impact** on patient **clinical outcomes**.

Prior Authorization Burden Has Increased

- Ninety-one percent of neurosurgeons report that the **burden** associated with prior authorization has **significantly increased** over the past five years.
- Insurers have increased the use of prior authorization over the past years for **procedures** (95%); for **diagnostic tools** (93%); and for **prescription medications** (55%).
- The burden associated with prior authorization for neurosurgeons and their staff is **high** or **extremely high** (95%).
- In any given week, most neurosurgeons (41%) must contend with between 11 and 40 prior authorizations. More than one-quarter (27%) of respondents face more than 40 per week.
- Many neurosurgeons must now engage in the so-called **peer-to-peer process** to obtain prior authorization, and nearly one-third (32%) of respondents experience this requirement for 26 to 75% or more of their services (including prescription drugs, diagnostic tests and medical services).
- Ultimately, the **majority of services are approved** (80%), with nearly forty percent (39%) of neurosurgeons getting approved 90% or more of the time.
- Unbelievably, despite gaining prior authorization, insurance companies **deny payment** after services are rendered, an outcome three-fifths of neurosurgeons have experienced more than once in the past year, and 24% have had this happen 20 or more times.
- More than three-fifths (62%) of neurosurgeons have staff members working **exclusively** on prior authorization, with most staff spending between 10-20 hours per week on prior authorization.
- **Most plans** employ prior authorization, although UnitedHealthcare (72%), Blue Cross Blue Shield (72%) and Aetna 68%) are the top utilizers.

Demographics

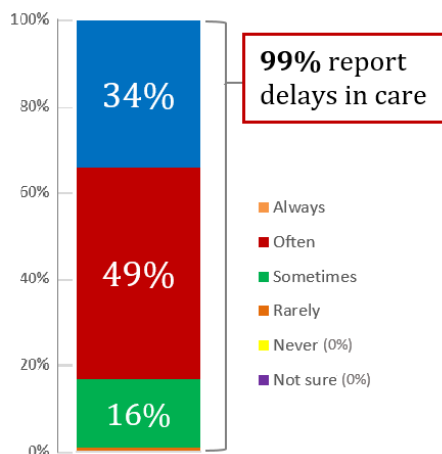
- Forty-two percent of respondents are from the South; 15% from the Northeast; 29% from the Midwest; and 14% from the West and U.S. Territories.
- Forty-one percent of respondents are in private practice; 11% are in private practice with an academic affiliation; 31% are in academic practice; and 16% are employed by a hospital or health system.
- Eleven percent of respondents are in solo practice; 23% are in a small group (2-5 physicians) single specialty practice; 26% are in a medium (6-20 physicians) group single specialty practice; 10% are in a large group (21+) single specialty practice; and the remaining (30%) are in multi-specialty group practices.
- Fifty-nine percent of respondents practice in an urban setting; 35% practicing in a suburban setting; while only 6% are in rural practice.

Prior Authorization is Putting Patients at Risk and Increasing Physician Burden

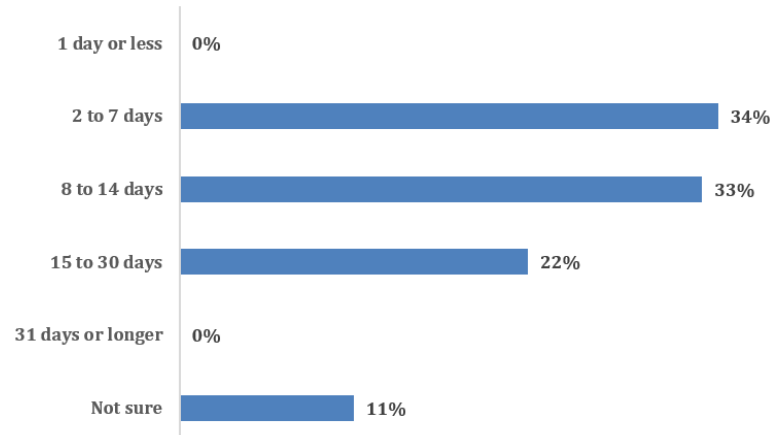
Patient Access to Care Has Been Adversely Impacted

Nearly all respondents state that prior authorization causes **delays in access** to necessary care, and the **wait time** for prior authorization can be lengthy. For most neurosurgeons (67%) it takes between 2 to 14 days to obtain prior authorization, but for 22%, this process can take from 15 to more than 31 days.

Q. For those patients whose treatment requires prior authorization, how often does this process delay access to necessary care?

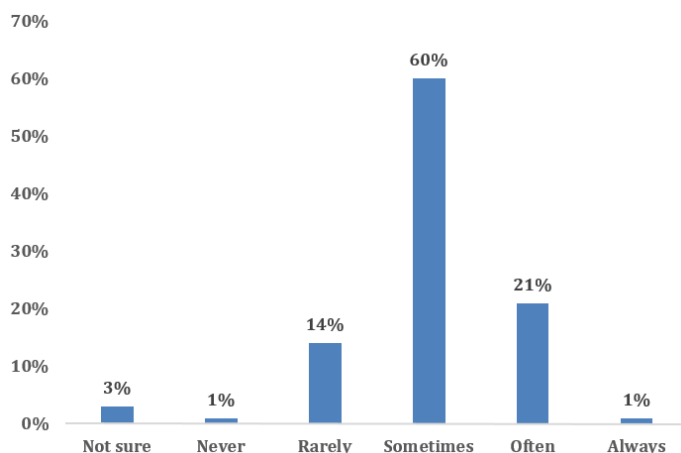


Q. What is the average length of time to obtain prior authorization after all required documentation has been submitted?

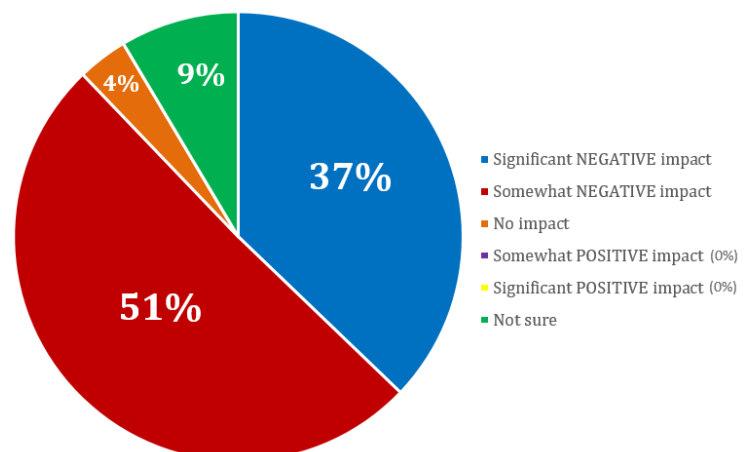


A majority of neurosurgeons reported that prior authorization causes patients to **abandon treatment** altogether, with 21% reporting that patients often abandon treatment and 60% reporting that patients sometimes abandon treatment. Overwhelmingly (88%), physicians report that prior authorization has a **negative impact** on patient **clinical outcomes**.

Q. For those patients whose treatment requires prior authorization, how often do issues related to this process lead to patients abandoning their recommended course of treatment?



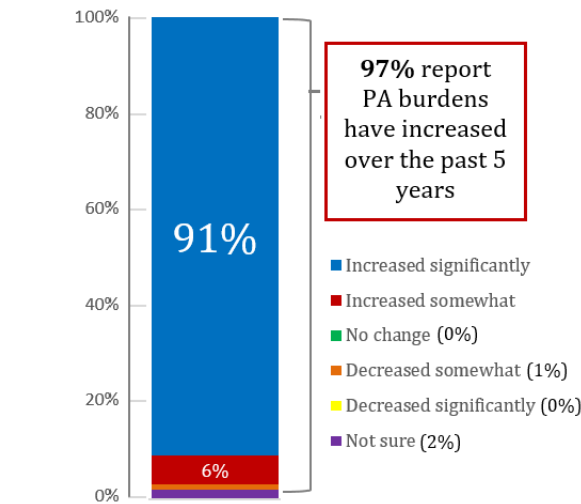
Q. For those patients whose treatment requires prior authorization, what is the impact of this process on patient clinical outcomes?



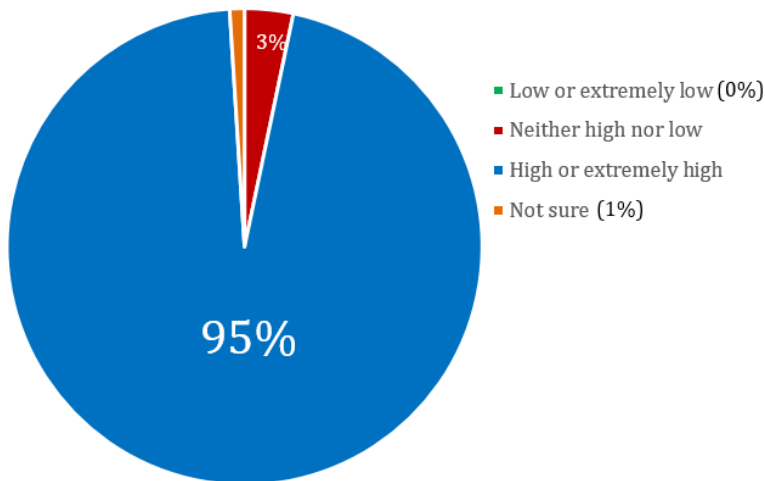
The Burden of Prior Authorization on Physicians Has Increased

Most neurosurgeons (91%) report that the **burden** associated with prior authorization has **significantly increased** over the past five years as insurers have increased the use of prior authorization for procedures (95%); for diagnostic tools (93%); and for prescription medications (55%). The burden associated with prior authorization for neurosurgeons and their staff is now **high** or **extremely high** (95%).

Q. How has the burden associated with prior authorization changed over the last five years for the physicians and staff in your practice?

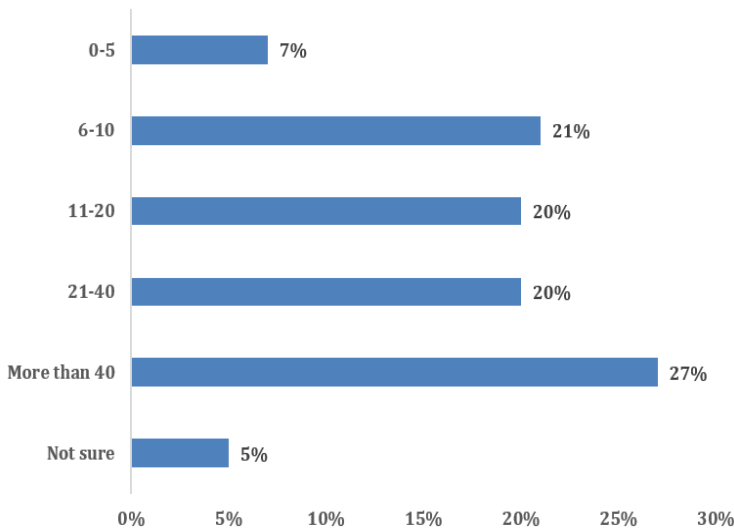


Q. How would you describe the burden associated with prior authorization for the physicians and staff in your practice?



In any given week, most neurosurgeons (41%) must contend with between 11 and 40 prior authorizations. More than one-quarter (27%) of respondents face more than 40 per week. Many physicians must now engage in the so-called **peer-to-peer** process — meaning after they go through an extensive paperwork process they must first speak directly to a clinician working for the health plan — to obtain prior authorization, and nearly 32% of respondents experience this requirement for 26-75% or more of their services (including prescription drugs, diagnostic tests and medical services).

Q. Please provide your best estimate of the number of prior authorizations (total for prescription medicine, diagnostic tests and medical services) completed by yourself and/or your staff for your patients in the last week.



32% of neurosurgeons go to “peer-to-peer” review for **26-75%** or more of their prior authorizations—and frequently the reviewer is not in the same or similar specialty

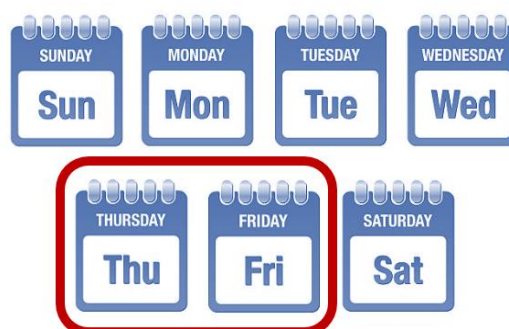


Ultimately, the **majority of services are approved** (80%), with nearly forty percent (39%) of neurosurgeons getting approved 90% or more of the time. Unbelievably, despite gaining prior authorization, insurance companies **deny payment after services are rendered**, an outcome three-fifths of neurosurgeons have experienced more than once in the past year, and 24% have had this happen 20 or more times.



More than three-fifths of neurosurgeons have staff members **working exclusively** on prior authorization

Physicians and their staff spend the equivalent of at least **two days** on prior authorization each week.



Survey Methodology

A 27-question, web-based survey was administered from November 2018 through January 2019.

Forty-two percent of respondents are from the South; 15% from the Northeast; 29% from the Midwest; and 14% from the West and U.S. Territories. Forty-one percent of respondents are in private practice; 11% are in private practice with an academic affiliation; 31% are in academic practice; and 16% are employed by a hospital or health system. Eleven percent of respondents are in solo practice; 23% are in a small group (2-5 physicians) single specialty practice; 26% are in a medium (6-20 physicians) group single specialty practice; 10% are in a large group (21+) single specialty practice; and the remaining (30%) are in multi-specialty group practices. Fifty-nine percent of respondents practice in an urban setting; 35% practicing in a suburban setting; while only 6% are in rural practice.

About the AANS and CNS

The American Association of Neurological Surgeons (AANS), founded in 1931, and the Congress of Neurological Surgeons (CNS), founded in 1951, are the two largest scientific and educational associations for neurosurgical professionals in the world. These groups represent over 8,000 neurosurgeons worldwide. Neurological surgery is the medical specialty concerned with the prevention, diagnosis, treatment and rehabilitation of disorders that affect the entire nervous system, including the spinal column, spinal cord, brain and peripheral nerves. For more information, please visit www.aans.org or www.cns.org, read our blog www.neurosurgeryblog.org, or follow us on Twitter @neurosurgery.

More Information

For more information about the AANS/CNS prior authorization survey, please contact:

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ATTACHMENT 2: Prior Authorization and Utilization Management Reform Principles

American Medical
Association

American Academy
of Child and
Adolescent
Psychiatry

American Academy
of Dermatology

American Academy
of Family
Physicians

American College of
Cardiology

American College of
Rheumatology

American Hospital
Association

American
Pharmacists
Association

American Society of
Clinical Oncology

Arthritis Foundation

Colorado Medical
Society

Medical Group
Management
Association

Medical Society of
the State of New
York

Minnesota Medical
Association

North Carolina
Medical Society

Ohio State Medical
Association

Washington State
Medical Association

Prior Authorization and Utilization Management Reform Principles

Patient-centered care has emerged as a major common goal across the health care industry. By empowering patients to play an active role in their care and assume a pivotal role in developing an individualized treatment plan to meet their health care needs, this care model can increase patients' satisfaction with provided services and ultimately improve treatment quality and outcomes.

Yet despite these clear advantages to adopting patient-centered care, health care providers and patients often face significant obstacles in putting this concept into practice. Utilization management programs, such as prior authorization and step therapy, can create significant barriers for patients by delaying the start or continuation of necessary treatment and negatively affecting patient health outcomes. The very manual, time-consuming processes used in these programs burden providers (physician practices, pharmacies and hospitals) and divert valuable resources away from direct patient care. However, health plans and benefit managers contend that utilization management programs are employed to control costs and ensure appropriate treatment.

Recognizing the investment that the health insurance industry will continue to place in these programs, a multi-stakeholder group representing patients, physicians, hospitals and pharmacists (see organizations listed in left column) has developed the following principles on utilization management programs to reduce the negative impact they have on patients, providers and the health care system. **This group strongly urges health plans, benefit managers and any other party conducting utilization management (“utilization review entities”), as well as accreditation organizations, to apply the following principles to utilization management programs for both medical and pharmacy benefits.** We believe adherence to these principles will ensure that patients have timely access to treatment and reduce administrative costs to the health care system.

Clinical Validity

1. Health care providers want nothing more than to provide the most clinically appropriate care for each individual patient. Utilization management programs must therefore have a clinically accurate foundation for provider adherence to be feasible. Cost-containment provisions that do not have proper medical justification can put patient outcomes in jeopardy.

Principle #1: Any utilization management program applied to a service, device or drug should be based on accurate and up-to-date clinical criteria and never cost alone. The referenced clinical information should be readily available to the prescribing/ordering provider and the public.

2. The most appropriate course of treatment for a given medical condition depends on the patient's unique clinical situation and the care plan developed by the provider in consultation with his/her patient. While a particular drug or therapy might generally be considered appropriate for a condition, the presence of comorbidities or patient intolerances, for example, may necessitate an alternative treatment. Failure to account for this can obstruct proper patient care.

Principle #2: Utilization management programs should allow for flexibility, including the timely overriding of step therapy requirements and appeal of prior authorization denials.

3. Adverse utilization management determinations can prevent access to care that a health care provider, in collaboration with his/her patient and the care team, has determined to be appropriate and medically necessary. As this essentially equates to the practice of medicine by the utilization review entity, it is imperative that these clinical decisions are made by providers who are at least as qualified as the prescribing/ordering provider.

Principle #3: Utilization review entities should offer an appeals system for their utilization management programs that allows a prescribing/ordering provider direct access, such as a toll-free number, to a provider of the same training and specialty/subspecialty for discussion of medical necessity issues.

Continuity of Care

4. Patients forced to interrupt ongoing treatment due to health plan utilization management coverage restrictions could experience a negative impact on their care and health. In the event that, at the time of plan enrollment, a patient's condition is stabilized on a particular treatment that is subject to prior authorization or step therapy protocols, a utilization review entity should permit ongoing care to continue while any prior authorization approvals or

step-therapy overrides are obtained.

Principle #4: Utilization review entities should offer a minimum of a 60-day grace period for any step-therapy or prior authorization protocols for patients who are already stabilized on a particular treatment upon enrollment in the plan. During this period, any medical treatment or drug regimen should not be interrupted while the utilization management requirements (e.g., prior authorization, step therapy overrides, formulary exceptions, etc.) are addressed.

5. Many patients carefully review formularies and coverage restrictions prior to purchasing a health plan product in order to ensure they select coverage that best meets their medical and financial needs. Unanticipated changes to a formulary or coverage restriction throughout the plan year can negatively impact patients' access to needed medical care and unfairly reduce the value patients receive for their paid premiums.

Principle #5: A drug or medical service that is removed from a plan's formulary or is subject to new coverage restrictions after the beneficiary enrollment period has ended should be covered without restrictions for the duration of the benefit year.

6. Many conditions require ongoing treatment plans that benefit from strict adherence. Recurring prior authorizations requirements can lead to gaps in care delivery and threaten a patient's health.

Principle #6: A prior authorization approval should be valid for the duration of the prescribed/ordered course of treatment.

7. Many utilization review entities employ step therapy protocols, under which patients are required to first try and fail certain therapies before qualifying for coverage of other treatments. These programs can be particularly problematic for patients—such as those purchasing coverage on the individual marketplace—who change health insurance on an annual basis. Patients who change health plans are often required to disrupt their current treatment to retry previously failed therapeutic regimens to meet step therapy requirements for the new plan. Forcing patients to abandon effective treatment and repeat therapy that has already been proven ineffective under other plans' step therapy protocols delays care and may result in negative health outcomes.

Principle #7: No utilization review entity should require patients to repeat step therapy protocols or retry therapies failed under other benefit plans before qualifying for coverage of a current effective therapy.

Transparency and Fairness

8. Prior authorization requirements and drug formulary changes can have a direct impact on patient care by creating a delay or altering the course of treatment. In order to ensure that patients and health care providers are fully informed while purchasing a product and/or making care decisions, utilization review entities need to be transparent about all coverage and formulary restrictions and the supporting clinical documentation needed to meet utilization management requirements.

Principle #8: Utilization review entities should publically disclose, in a searchable electronic format, patient-specific utilization management requirements, including prior authorization, step therapy, and formulary restrictions with patient cost-sharing information, applied to individual drugs and medical services. Such information should be accurate and current and include an effective date in order to be relied upon by providers and patients, including prospective patients engaged in the enrollment process. Additionally, utilization review entities should clearly communicate to prescribing/ordering providers what supporting documentation is needed to complete every prior authorization and step therapy override request.

9. Incorporation of accurate formulary data and prior authorization and step therapy requirements into electronic health records (EHRs) is critical to ensure that providers have the requisite information at the point of care. When prescription claims are rejected at the pharmacy due to unmet prior authorization requirements, treatment may be delayed or completely abandoned, and additional administrative burdens are imposed on prescribing providers and pharmacies/pharmacists.

Principle #9: Utilization review entities should provide, and vendors should display, accurate, patient-specific, and up-to-date formularies that include prior authorization and step therapy requirements in electronic health record (EHR) systems for purposes that include e-prescribing.

10. Data are critical to evaluating the effectiveness, potential impact and costs of prior authorization processes on patients, providers, health insurers and the system as a whole; however, limited data are currently made publically available for research and analysis. Utilization review entities need to provide industry stakeholders with relevant data, which should be used to improve efficiency and timely access to clinically appropriate care.

Principle #10: Utilization review entities should make statistics regarding prior authorization approval and denial rates available on their website (or another publically available website) in a readily accessible format. The statistics shall include but are not limited to the following categories related to prior authorization requests:

- i. Health care provider type/specialty;
- ii. Medication, diagnostic test or procedure;
- iii. Indication;
- iv. Total annual prior authorization requests, approvals and denials;
- v. Reasons for denial such as, but not limited to, medical necessity or incomplete prior authorization submission; and
- vi. Denials overturned upon appeal.

These data should inform efforts to refine and improve utilization management programs.

11. A planned course of treatment is the result of careful consideration and collaboration between patient and physician. A utilization review entity's denial of a drug or medical service requires deviation from this course. In order to promote provider (physician practice, hospital and pharmacy) and patient understanding and ensure appropriate clinical decision-making, it is important that utilization review entities provide specific justification for prior authorization and step therapy override denials, indicate any covered alternative treatment and detail any available appeal options.

Principle #11: Utilization review entities should provide detailed explanations for prior authorization or step therapy override denials, including an indication of any missing information. All utilization review denials should include the clinical rationale for the adverse determination (e.g., national medical specialty society guidelines, peer-reviewed clinical literature, etc.), provide the plan's covered alternative treatment and detail the provider's appeal rights.

Timely Access and Administrative Efficiency

12. The use of standardized electronic prior authorization transactions saves patients, providers and utilization review entities significant time and resources and can speed up the care delivery process. In order to ensure that prior authorization is conducted efficiently for all stakeholders, utilization review entities need to complete all steps of utilization management processes through NCPDP SCRIPT ePA transactions for pharmacy benefits and the ASC X12N 278 Health Care Service Review Request for Review and Response transactions for medical services benefits. Proprietary health plan web-based portals do not represent efficient automation or true administrative simplification, as they require health care

providers to manage unique logins/passwords for each plan and manually re-enter patient and clinical data into the portal.

Principle #12: A utilization review entity requiring health care providers to adhere to prior authorization protocols should accept and respond to prior authorization and step-therapy override requests exclusively through secure electronic transmissions using the standard electronic transactions for pharmacy and medical services benefits. Facsimile, proprietary payer web-based portals, telephone discussions and nonstandard electronic forms shall not be considered electronic transmissions.

13. Providers have encountered instances where utilization review entities deny payment for previously approved services or drugs based on criteria outside of the prior authorization review process (e.g., eligibility issues, medical policies, etc.). These unexpected payment denials create hardship for patients and additional administrative burdens for providers.

Principle #13: Eligibility and all other medical policy coverage determinations should be performed as part of the prior authorization process. Patients and physicians should be able to rely on an authorization as a commitment to coverage and payment of the corresponding claim.

14. Significant time and resources are devoted to completing prior authorization requirements to ensure that the patient will have the requisite coverage. If utilization review entities choose to use such programs, they need to honor their determinations to avoid misleading and further burdening patients and health care providers. Prior authorization must remain valid and coverage must be guaranteed for a sufficient period of time to allow patients to access the prescribed care. This is particularly important for medical procedures, which often must be scheduled and approved for coverage significantly in advance of the treatment date.

Principle #14: In order to allow sufficient time for care delivery, a utilization review entity should not revoke, limit, condition or restrict coverage for authorized care provided within 45 business days from the date authorization was received.

15. In order to ensure that patients have prompt access to care, utilization review entities need to make coverage determinations in a timely manner. Lengthy processing times for prior authorizations can delay necessary treatment, potentially creating pain and/or medical complications for patients.

Principle #15: If a utilization review entity requires prior authorization for non-urgent care, the entity should make a determination and notify the provider within 48 hours of obtaining all necessary information. For urgent care, the determination should be made within 24 hours of obtaining all necessary information.

16. When patients receive an adverse determination for care, the patient (or the physician on behalf of the patient) has the right to appeal the decision. The utilization review entity has a responsibility to ensure that the appeals process is fair and timely.

Principle #16: Should a provider determine the need for an expedited appeal, a decision on such an appeal should be communicated by the utilization review entity to the provider and patient within 24 hours. Providers and patients should be notified of decisions on all other appeals within 10 calendar days. All appeal decisions should be made by a provider who (a) is of the same specialty, and subspecialty, whenever possible, as the prescribing/ordering provider and (b) was not involved in the initial adverse determination.

17. Prior authorization requires administrative steps in advance of the provision of medical care in order to ensure coverage. In emergency situations, a delay in care to complete administrative tasks related to prior authorization could have drastic medical consequences for patients.

Principle #17: Prior authorization should never be required for emergency care.

18. There is considerable variation between utilization review entities' prior authorization criteria and requirements and extensive use of proprietary forms. This lack of standardization is associated with significant administrative burdens for providers, who must identify and comply with each entity's unique requirements. Furthermore, any clinically based utilization management criteria should be similar—if not identical—across utilization review entities.

Principle #18: Utilization review entities are encouraged to standardize criteria across the industry to promote uniformity and reduce administrative burdens.

Alternatives and Exemptions

19. Broadly applied prior authorization programs impose significant administrative burdens on all health care providers, and for those providers with a clear history of appropriate resource utilization and high prior authorization approval rates, these burdens become especially unjustified.

Principle #19: Health plans should restrict utilization management programs to “outlier” providers whose prescribing or ordering patterns differ significantly from their peers after adjusting for patient mix and other relevant factors.

20. Prior authorization requirements are a burdensome way of confirming clinically appropriate care and managing utilization, adding administrative costs for all stakeholders across the health care system. Health plans should offer alternative, less costly options to serve the same functions.

Principle #20: Health plans should offer providers/practices at least one physician-driven, clinically based alternative to prior authorization, such as but not limited to “gold-card” or “preferred provider” programs or attestation of use of appropriate use criteria, clinical decision support systems or clinical pathways.

21. By sharing in the financial risk of resource allocation, providers engaged in new payment models are already incented to contain unnecessary costs, thus rendering prior authorization unnecessary.

Principle #21: A provider that contracts with a health plan to participate in a financial risk-sharing payment plan should be exempt from prior authorization and step-therapy requirements for services covered under the plan's benefits.

Additional Supporting Organizations

In addition to the authoring workgroup participants (listed on the first page), the following organizations have officially indicated support for the Prior Authorization and Utilization Management Reform Principles:

Accreditation Council for Pharmacy Education	American Association of Orthopaedic Surgeons	American Society for Radiation Oncology
Advocacy Council of the American College of Allergy, Asthma and Immunology	American College of Allergy, Asthma and Immunology	American Society for Surgery of the Hand
Alabama Pharmacy Association	American College of Apothecaries	American Society of Addiction Medicine
Allergy & Asthma Network	American College of Gastroenterology	American Society of Cataract and Refractive Surgery
American Academy of Neurology	American College of Medical Genetics and Genomics	American Society of Consultant Pharmacists
American Academy of Ophthalmology	American College of Osteopathic Family Physicians	American Society of Dermatopathology
American Academy of Pain Medicine	American College of Phlebology	American Society of Echocardiography
American Academy of Sleep Medicine	American College of Physicians	American Society of Health-System Pharmacists
American Academy of Physical Medicine and Rehabilitation	American Orthopaedic Foot & Ankle Society	American Society of Hematology
American Association of Clinical Urologists	American Osteopathic Association	American Society of Plastic Surgeons
American Association of Colleges of Pharmacy	American Physical Therapy Association	American Society of Retina Specialists
American Association of Neurological Surgeons	American Psychiatric Association	American Society of Transplant Surgeons
American Association of Neuromuscular & Electrodiagnostic Medicine	American Society for Metabolic and Bariatric Surgery	American Urological Association
		Arizona Pharmacy Association

**California Academy of Child
and Adolescent Psychiatry**

**Coalition of State
Rheumatology
Organizations**

**College of Psychiatric and
Neurologic Pharmacists**

**Colorado Child and
Adolescent Psychiatric
Society**

**Congress of
Neurological Surgeons**

**Connecticut State Medical
Society**

**Delaware Council of Child
and Adolescent Psychiatry**

**Dutchess County Medical
Society**

Florida Medical Association

**Florida Pharmacy
Association**

**Georgia Council on Child
and Adolescent Psychiatry**

**Global Healthy Living
Foundation**

Hawaii Medical Association

**Hematology/Oncology
Pharmacy Association**

Idaho Medical Association

**Illinois Council of Child and
Adolescent Psychiatry**

**Illinois Pharmacists
Association**

**Illinois State Medical
Society**

**Indiana Council of Child
Psychiatry**

**Indiana State Medical
Association**

**International Society for the
Advancement of Spine
Surgery**

Iowa Medical Society

**Iowa Pharmacy
Association**

**Kentucky Medical
Association**

**Maine Council of Child and
Adolescent Psychiatry**

Maine Medical Association

**Massachusetts Medical
Society**

**MedChi, The Maryland State
Medical Society**

**Medical Association
of Georgia**

**Medical Association of the
State of Alabama**

Medical Society of Delaware

**Medical Society of New
Jersey**

Medical Society of Virginia

**Michigan Council of Child
and Adolescent Psychiatry**

**Mississippi State Medical
Association**

**Missouri State Medical
Association**

**Monroe County Medical
Society**

**Montana Medical
Association**

**National Alliance of State
Pharmacy Associations**

**National Community
Pharmacy Association**

**Nebraska Medical
Association**

**New Hampshire Medical
Society**

**New Jersey Council of
Child and Adolescent
Psychiatry**

**New Mexico Council of
Child and Adolescent
Psychiatry**

**New Mexico Medical
Society**

**New Mexico Pharmacists
Association**

**New York Council of Child
and Adolescent Psychiatry**

**North American Spine
Society**

**North Central Florida
Council of Child &
Adolescent Psychiatry**

**North Dakota Medical
Association**

**Oklahoma State Medical
Association**

**Oregon Medical
Association**

**Pennsylvania Medical
Society**

**Pennsylvania Pharmacists
Association**

**Regional Council of Child
and Adolescent Psychiatry
of Eastern Pennsylvania &
Southern New Jersey**

**Renal Physicians
Association**

**Rhode Island Council for
Child and Adolescent
Psychiatry**

**Rhode Island Medical
Society**

**Saratoga County Medical
Society**

**Society of Hospital
Medicine**

**Society of Interventional
Radiology**

**South Carolina Medical
Association**

**South Dakota State Medical
Association**

**Tennessee Medical
Association**

Texas Medical Association

**Texas Pharmacy
Association**

**Texas Society of Child and
Adolescent Psychiatry**

Utah Medical Association

Vermont Medical Society

**Virginia Council of Child
Psychiatry**

**Westchester County
Medical Society**

Wyoming Medical Society

ATTACHMENT 3: Consensus Statement on Improving the Prior Authorization Process



Consensus Statement on Improving the Prior Authorization Process

Our organizations represent health care providers (physicians, pharmacists, medical groups, and hospitals) and health plans. We have partnered to identify opportunities to improve the prior authorization process, with the goals of promoting safe, timely, and affordable access to evidence-based care for patients; enhancing efficiency; and reducing administrative burdens. The prior authorization process can be burdensome for all involved—health care providers, health plans, and patients. Yet, there is wide variation in medical practice and adherence to evidence-based treatment. Communication and collaboration can improve stakeholder understanding of the functions and challenges associated with prior authorization and lead to opportunities to improve the process, promote quality and affordable health care, and reduce unnecessary burdens.

The following five areas offer opportunities for improvement in prior authorization programs and processes that, once implemented, can achieve meaningful reform.

- 1. Selective Application of Prior Authorization.** Differentiating the application of prior authorization based on provider performance on quality measures and adherence to evidence-based medicine or other contractual agreements (i.e., risk-sharing arrangements) can be helpful in targeting prior authorization requirements where they are needed most and reducing the administrative burden on health care providers. Criteria for selective application of prior authorization requirements may include, for example, ordering/prescribing patterns that align with evidence-based guidelines and historically high prior authorization approval rates.

We agree to:

- ***Encourage the use of programs that selectively implement prior authorization requirements based on stratification of health care providers' performance and adherence to evidence-based medicine***
- ***Encourage (1) the development of criteria to select and maintain health care providers in these selective prior authorization programs with the input of contracted health care providers and/or provider organizations; and (2) making these criteria transparent and easily accessible to contracted providers***

- *Encourage appropriate adjustments to prior authorization requirements when health care providers participate in risk-based payment contracts*

2. **Prior Authorization Program Review and Volume Adjustment.** Regular review of the list of medical services and prescription drugs that are subject to prior authorization requirements can help identify therapies that no longer warrant prior authorization due to, for example, low variation in utilization or low prior authorization denial rates. Regular review can also help identify services, particularly new and emerging therapies, where prior authorization may be warranted due to a lack of evidence on effectiveness or safety concerns.

We agree to:

- *Encourage review of medical services and prescription drugs requiring prior authorization on at least an annual basis, with the input of contracted health care providers and/or provider organizations*
- *Encourage revision of prior authorization requirements, including the list of services subject to prior authorization, based on data analytics and up-to-date clinical criteria*
- *Encourage the sharing of changes to the lists of medical services and prescription drugs requiring prior authorization via (1) provider-accessible websites; and (2) at least annual communications to contracted health care providers*

3. **Transparency and Communication Regarding Prior Authorization.** Effective, two-way communication channels between health plans, health care providers, and patients are necessary to ensure timely resolution of prior authorization requests to minimize care delays and clearly articulate prior authorization requirements, criteria, rationale, and program changes.

We agree to:

- *Improve communication channels between health plans, health care providers, and patients*
- *Encourage transparency and easy accessibility of prior authorization requirements, criteria, rationale, and program changes to contracted health care providers and patients/enrollees*
- *Encourage improvement in communication channels to support (1) timely submission by health care providers of the complete information necessary to make a prior authorization determination as early in the process as possible; and (2) timely notification of prior authorization determinations by health plans to impacted health care providers (both ordering/rendering physicians and dispensing pharmacists) and patients/enrollees*

4. **Continuity of Patient Care.** Continuity of patient care is vitally important for patients undergoing an active course of treatment when there is a formulary or treatment coverage

change and/or a change of health plan. Additionally, access to prescription medications for patients on chronic, established therapy can be affected by prior authorization requirements. Although multiple standards addressing timeliness, continuity of care, and appeals are currently in place, including state and federal law and private accreditation standards, additional efforts to minimize the burdens and patient care disruptions associated with prior authorization should be considered.

We agree to:

- ***Encourage sufficient protections for continuity of care during a transition period for patients undergoing an active course of treatment when there is a formulary or treatment coverage change or change of health plan that may disrupt their current course of treatment***
- ***Support continuity of care for medical services and prescription medications for patients on appropriate, chronic, stable therapy through minimizing repetitive prior authorization requirements***
- ***Improve communication between health care providers, health plans, and patients to facilitate continuity of care and minimize disruptions in needed treatment***

5. **Automation to Improve Transparency and Efficiency.** Moving toward industry-wide adoption of electronic prior authorization transactions based on existing national standards has the potential to streamline and improve the process for all stakeholders. Additionally, making prior authorization requirements and other formulary information electronically accessible to health care providers at the point-of-care in electronic health records (EHRs) and pharmacy systems will improve process efficiencies, reduce time to treatment, and potentially result in fewer prior authorization requests because health care providers will have the coverage information they need when making treatment decisions. Technology adoption by all involved stakeholders, including health care providers, health plans, and their trading partners/vendors, is key to achieving widespread industry utilization of standard electronic prior authorization processes.

We agree to:

- ***Encourage health care providers, health systems, health plans, and pharmacy benefit managers to accelerate use of existing national standard transactions for electronic prior authorization (i.e., National Council for Prescription Drug Programs [NCPDP] ePA transactions and X12 278)***
- ***Advocate for adoption of national standards for the electronic exchange of clinical documents (i.e., electronic attachment standards) to reduce administrative burdens associated with prior authorization***
- ***Advocate that health care provider and health plan trading partners, such as intermediaries, clearinghouses, and EHR and practice management system vendors, develop and deploy software and processes that facilitate prior authorization automation using standard electronic transactions***
- ***Encourage the communication of up-to-date prior authorization and step therapy requirements, coverage criteria and restrictions, drug tiers, relative***

costs, and covered alternatives (1) to EHR, pharmacy system, and other vendors to promote the accessibility of this information to health care providers at the point-of-care via integration into ordering and dispensing technology interfaces; and (2) via websites easily accessible to contracted health care providers