September 27, 2018

Demetrios Kouzoukas

Principal Deputy Administrator & Director of the Center for Medicare

Centers for Medicare & Medicaid Services

200 Independence Avenue, SW

Washington, DC 20201

Dear Mr. Kouzoukas:

On behalf of the Regulatory Relief Coalition, including the professional associations set forth below, thank you for taking the time to meet with us on September 5, 2018. We are encouraged to hear that you and your staff are taking a closer look at what CMS might do to improve prior authorization (PA) for the patients our physicians serve and the physicians our organizations represent. Per your recent request, and as outlined in our comments, correspondence, and meetings with CMS, we believe that these issues should be addressed by taking the four actions set forth below.

1. **GUIDANCE TO PLANS: CMS should issue guidance urging MA plans to follow the PA practices endorsed by America’s Health Insurance Plans (AHIP) and Blue Cross/Blue Shield Association (BC/BSA) and to adhere to applicable Medicare regulatory requirements.**

In January 2018, associations representing managed care plans (AHIP and BC/BSA) endorsed a statement of principles[[1]](#footnote-1) that identifies five areas that “offer opportunities for improvement in prior authorization programs and processes that, once implemented, can achieve meaningful reform.” These include, among other things:

* Selective Application of PA: MA plans should apply PA requirements selectively, exempting providers that meet evidence-based guidelines.
* Annual PA Program Review and Removal of Services for which PA is Unnecessary: Services involving low variation in utilization or low PA denial rates should be removed from PA lists.
* Assuring Continuity of Care: MA plans should minimize repetitive PA requirements for chronic conditions.

We urge CMS to issue a transmittal to MA plans that (a) specifically adopts the policies for PA reform set forth in the Consensus Statement; and (b) “flags” PA practices that will be considered inappropriate barriers to access.[[2]](#footnote-2)

The transmittal should also remind MA plans that they may not subsequently deny payment for a service that has been approved through a PA process, since the PA decision should resolve all issues related to payment.”

1. **STANDARIZATION OF PA TRANSACTIONS: CMS should finalize the Attachment Standard as soon as practicable and issue Model PA forms for PA submittals submitted via websites and manually.**

As you know, the administrative burden of PA processes is in part attributable to the lack of a uniform format for the submission of PA requests. To facilitate uniformity, we urge CMS to issue the Attachment Standard (278) as soon as practicable. We note, however, that, in order to alleviate their own administrative burdens pending the issuance of the Attachment Standard, MA plans are establishing their own proprietary websites, which are not subject to HIPAA transaction standards, but are required to mirror the content required by the transaction standards. In the absence of oversight or guidance, MA plans’ website tools — like their manual submittal processes — are individualized and idiosyncratic. We urge CMS to issue Model PA Forms to be utilized in conjunction with MA plans’ PA websites (direct data entry systems) and for manual submissions.

1. **DATA COLLECTION: CMS should require MA plans to report on the extent of their use of PA and the approval/denial rate by service and/or prescription medications.**

Reasonable resolution of provider and patient grievances with respect to PA requires comprehensive and specific information regarding MA plans’ PA processes and outcomes. This should include the submission of the following data as one component of MA plans’ annual reports to CMS:

* Data on the specific procedures and prescription medications subject to PA;
* The proportion of each service and prescription medication approved; and
* The time elapsed from submission until the issuance of an organization determination.

Without this data, CMS policymaking or congressional oversight necessarily would be formulated “in the dark.”

1. **OVERSIGHT: CMS should exercise ongoing oversight over MA plans PA processes.**

Without enhanced CMS oversight over MA plans’ PA processes, it is doubtful whether any meaningful progress will be achieved. MA plans’ PA processes should be reviewed based on clear criteria and their performance made public on the CMS website, based on information gathered through:

* MA plan annual reports; and
* Special focus audits.

We would be delighted to work with you on the criteria we believe would be of interest to patients and providers.

We look forward to hearing from you soon regarding the actions that CMS intends to take regarding this important issue.

Sincerely yours,

American Academy of Neurology

American Academy of Ophthalmology

American Association of Neurological Surgeons/

Congress of Neurological Surgeons

American College of Cardiology

American College of Rheumatology

American College of Surgeons

American Urological Association

American Society of Clinical Oncology

Enclosure



**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***

1. **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***

1. **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***

1. **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***

1. **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***

1. Consensus Statement on Improving the Prior Authorization Process (*See* attached). [↑](#footnote-ref-1)
2. These include, for example, implementing PA policies that are inconsistent with local or national LCDs; requiring repetitive PA for chronic conditions; requiring PA for items and services that are part of a plan of care that has already been approved; denying payment for failure to obtain PA for a service that is performed during the course of an approved surgical procedure.) [↑](#footnote-ref-2)