



October 28, 2021

The Honorable Chiquita Brooks-LaSure, Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Dear Administrator Chiquita Brooks-LaSure:

The undersigned members of the Regulatory Relief Coalition, representing thousands of physicians throughout the United States, are writing to request a meeting with you and your staff to discuss the Center for Medicare & Medicaid's (CMS) utilization review policies, particularly those related to prior authorization (PA). The RRC is a group of national physician specialty organizations advocating for regulatory burden reduction so that physicians can spend more time treating patients. Our aim is to ensure that utilization review policies are not a barrier to timely and equitable access to care for the patients we serve.

As more fully described below, in recent years, CMS has significantly expanded authority for various utilization review tools in the Medicare Advantage (MA) and Medicare Fee-for-Service (FFS) programs. These include:

- PA for a broad array of physician services in MA;
- PA for seven medical services performed in the hospital outpatient department setting in Medicare FFS;
- Appropriate Use Criteria (AUC) for advanced diagnostic imaging in Medicare FFS; and
- Step therapy for Part B drugs covered by MA plans

In addition, the previous Administration had issued a proposed rule to reduce provider and patient burden by improving PA processes in Medicaid, the Children's Health Insurance Program (CHIP), and the individual market, including electronic PA.¹ Unfortunately, CMS never finalized this rule, adding to the continued burdens associated with prior authorization.

Give the myriad programs, which are undertaken by different departments within CMS, we urge you to conduct an agency-wide review of utilization review policies in Medicare, Medicaid/CHIP, and the individual market and take such action as may be necessary to ensure that these programs do not raise unnecessary barriers to care for beneficiaries.

¹ RIN 0938-AT99, Medicaid Program; Patient Protection and Affordable Care Act; Reducing Provider and Patient Burden by Improving Prior Authorization Processes, and Promoting Patients' Electronic Access to Health Information for Medicaid Managed Care Plans, State Medicaid Agencies, CHIP Agencies and CHIP Managed Care Entities, and Issuers of Qualified Health Plans on the Federally-facilitated Exchanges; Health Information Technology Standards and Implementation Specifications, Published in the *Federal Register* on Dec. 18, 2020.

Background

Widespread Use of Prior Authorization is Costly, Delays Necessary Care, and May Worsen Health Care Inequities

Historically, managed care plans used PA primarily to control the utilization of new treatments, drugs² and imaging services. Over the past 10 years, health insurers have substantially increased the use of PA in an effort to reduce health care costs. For example, the CAQH 2018 Index (Report of Healthcare Industry Electronic Business Transactions and Adoption) estimates a 14 percent increase in the national volume of prior authorization transactions compared to the 2017 report and a 27 percent increase compared to the 2016 report. Due to these significant increases, patients are now experiencing significant barriers to medically necessary care due to PA requirements for services that are eventually and routinely approved. In some instances, PA is imposed on services — such as transplantation, procedures for blinding eye disease or cancer care — that are very unlikely to be over-utilized and are eventually approved 90-100% of the time. In these and other cases, PA not only expends unnecessary time and money for plans, providers, and caregivers, but it often prevents beneficiaries from receiving medically necessary — sometimes lifesaving — care in a timely manner. Studies also suggest that PA exacerbates existing health inequities for underserved patients, as well as Black and other patients of color.³

Moreover, the widespread use of PA significantly increases provider costs. The direct costs — not including the costs of collecting, transmitting and reviewing relevant clinical information or overhead — are over \$13 per manual transaction and over \$7 per transaction conducted via proprietary payer portals. This only includes the cost of the time spent on the phone by health plans and providers, likely comprising substantially less than half of the overall costs. An estimated 185 million PA transactions took place in 2020, costing providers and payers \$767 million in direct costs alone, with 86% of this cost borne by providers. And this estimate does not include the costs of electronic PA requests. We estimate that overall costs are likely at least double this amount.

Most importantly, PA has a significant impact on clinical care. Consider the following from a recent RRC survey:⁴

- For most physicians (74%), it takes between 2 to 14 days to obtain PA, but for 15%, this process can take from 15 to more than 31 days;
- A majority of physicians report that PA forces some patients to abandon treatment altogether, and physicians overwhelmingly (87%) report that PA has a negative impact on patient clinical outcomes;
- Most physicians (84%) report that the burden associated with PA has significantly increased over the past five years as insurers have increased the use of PA for procedures (84%); for diagnostic tools (78%); and for prescription medications (80%); and

² Based on one analysis, health care costs associated with prior authorizations exceed the benefits of reduced drug spending increasing total health care spending by \$1.9 billion per year. <https://www.hsj.gr/medicine/an-estimate-of-the-net-benefits-from-prior-authorization-policies-in-the-us.pdf>.

³ Available at <http://abcario.org/wp-content/uploads/2019/03/AB-20190227-PA-White-Paper-Survey-Results-final.pdf>.

⁴ Available at <https://www.regrelief.org/wp-content/uploads/2019/12/RRC-Prior-Authorization-Survey-Results-FINAL-7-26.pdf>.

- The burden associated with PA for physicians and their staff is now high or extremely high (92%), and in any given week, most physicians (42%) must contend with between 11 and 40 PA requests.

These findings are consistent with other research, including work conducted by the American Medical Association.⁵ Notably, associations representing health plans, including America's Health Insurance Plans (AHIP) and the Blue Cross/Blue Shield Association (BC/BS), have recognized the need to streamline and simplify PA processes. These associations, along with several national provider groups, have started by adopting the *Consensus Statement on Improving the Prior Authorization Process*⁶ (*Consensus Statement*), which sets forth principles for designing and implementing PA programs. We believe that the Department of Health and Human Services (HHS) can play a critical role in ensuring that these principles become the industry standard, ultimately benefiting patients, providers, health plans and the federal programs alike.

CMS has Inappropriately Expanded Utilization Review in Medicare

Prior Authorization in Medicare Advantage

Despite all this, the use of PA by MA plans has grown unchecked. While the RRC repeatedly requested CMS to require MA plans to adhere to the *Consensus Statement* standards and to include a measure related to PA in the MA plan star ratings, no action was taken.

In addition, effective in 2019, CMS reversed a ban on step therapy policy adopted by the Obama Administration that protected patients. Instead, they finalized new regulations that authorize MA plans to impose coverage restrictions under which Medicare enrollees are required to fail on health-plan designated drugs before they are provided access to physician-prescribed drugs under Medicare Part B ("fail-first" or "step therapy").

Furthermore, the aforementioned electronic PA (e-PA) proposed rule issued in the waning days of the previous Administration excluded MA plans from e-PA that would have significantly improved PA processes. (CMS has pulled this e-PA rule from publication, and these rules remain under administrative review.)

Recognizing the problems associated with the expanded use of PA in the MA program, in 2018, more than 100 Members of Congress sent a letter to then CMS Administrator, Seema Verma, expressing concern about MA plans' use of PA, and asked CMS to collect data on the scope of PA practices to enable better oversight.⁷ Additionally, the HHS Office of the Inspector General (OIG) recently found that MA plans inappropriately deny care at relatively high rates.⁸ To the extent that the OIG findings are more

⁵ Available at <https://www.ama-assn.org/practice-management/sustainability/prior-authorization-research-reports>.

⁶ <https://www.mgma.com/getattachment/Government-Affairs/Issues-overview/Health-Information-Technology/Administrative-Simplification/Administrative-Simplification/Finalized-PA-consensus-statement-120717-logos.pdf>.

⁷ Available at <https://www.aans.org/-/media/Files/AANS/Advocacy/PDFS/Medicare-Advantage-Prior-Authorization-Letter-to-CMS---Signed.ashx>.

⁸ Office of Inspector General. *Medicare Advantage Appeal Outcomes and Audit Findings Raise Concerns About Service and Payment Denials* (OEI-09-16-00410). September 2018. Available at <https://oig.hhs.gov/oei/reports/oei-09-16-00410.asp>.

the norm than the exception, they raise concerns for enrollees and questions as to whether PA rules contribute to the relatively high rates⁹ of disenrollment¹⁰ among sicker MA enrollees.¹¹

Other Utilization Review Programs

The expanded use of PA over the past four years has not been limited to MA plans. As mentioned above, CMS has used its administrative discretion to require PA for certain hospital outpatient services provided to Medicare FFS beneficiaries. This expansion was adopted without adequate transparency regarding the standards used to select the services subject to these burdensome new requirements and in the face of evidence that the MACs were failing to process PA requests for the original five procedures within the required time frames. Physicians who have been subject to these PA requirements continue to experience significant challenges in obtaining timely approval, with some requests for medically necessary services taking three months to be approved. These approval delays result in other downstream barriers to PA approval, including repetitive requests from MACs for information that has already been provided, ultimately forcing physicians to delay medically necessary surgeries. While CMS has provided an exemption pathway from the PA program, implementation issues affecting initial PA approvals affect the implementation of this pathway since the availability of the exemption depends partly on the approval rate of initial requests.

The AUC Program for advanced imaging services, mandated by Congress in 2014 in the Protecting Access to Medicare Act, is yet another burdensome utilization management program. This is an untested payment and PA model that requires consultation and documentation by physicians and other health care professionals of AUC when an advanced imaging service is ordered for and provided to Medicare beneficiaries. Nearly seven years later, the AUC Program implementation and rulemaking are incomplete, prompting concerns about the law's complexity and the cost and regulatory burden incurred by physicians and other health care providers to meet program requirements if the program were ever to take effect — in whole or in part. Many of our member organizations have led the way with the development of AUC for diagnostic imaging, and they continue to advocate for its use. However, the burdens and costs of this program are untenable.¹²

Proposed CMS Actions

In light of these developments, we believe that these pressing PA issues warrant immediate and systematic review and reconsideration. These include:

⁹ Jacobson G, Neuman P, Damico A. *At Least Half Of New Medicare Advantage Enrollees Had Switched From Traditional Medicare During 2006–11*. *Health Aff.* 2015; 34(1). <https://doi.org/10.1377/hlthaff.2014.0218>.

¹⁰ Li Q, Trivedi A, Galarraga O, Chernew M, Weiner D, Mor V. *Medicare Advantage Ratings And Voluntary Disenrollment Among Patients With End-Stage Renal Disease*. *Health Aff.* 2018; 37(1). <https://doi.org/10.1377/hlthaff.2017.0974>.

¹¹ Government Accountability Office. *MEDICARE ADVANTAGE: CMS Should Use Data on Disenrollment and Beneficiary Health Status to Strengthen Oversight* (GAO-17-393). April 2017. Available at <https://www.gao.gov/assets/gao-17-393.pdf>.

¹² According to one estimate, it will cost \$75,000 or more for a practice to implement a clinical decision support mechanism to comply with the AUC Program rules. See the Association for Medical Imaging Management's 2017 CDS survey available at <https://ahralink.files.wordpress.com/2017/03/cds-survey-2017.pdf>.

Improve Oversight of MA Plans

MA plans' authority to impose PA requirements is not unlimited. The Medicare statute¹³ expressly requires that MA plans provide to MA enrollees the same Part A and Part B benefits provided to FFS Medicare beneficiaries (with limited statutorily defined exceptions). Likewise, applicable statute and regulations require that MA plans:

- Make available HIPAA compliant transaction standards for PA requests;
- Ensure that PA decisions are made by a physician or other medical professional with “sufficient medical and other expertise, including knowledge of Medicare coverage criteria;”
- Utilize physicians with expertise in the particular field of medicine involved for reconsideration requests; and
- Comply with strict timelines for initial processing and appeals of PA determinations.

In a Manual revision adopted in 2016, CMS indicated that, in reviewing Plan D sponsors' PA forms, CMS had identified several non-allowable practices, including, for example:

- Imposing requirements that were more restrictive than CMS-approved PA criteria or that were not disclosed to CMS at all;
- Imposing limits that were inconsistent with FDA dosage instructions; and
- Steering physicians or beneficiaries to a plan sponsor's and/or PBM's own mail order or specialty pharmacy.

We strongly believe that a comprehensive review of the forms and processes used by MA plans in conducting PA reviews of medical services would reveal similar deficiencies. Substantial additional scrutiny of PA practices related to medical procedures and services is overdue.

Adopt PA Standards for MA Plans

In light of the increased and increasing proportion of Medicare beneficiaries enrolled in MA plans and the ubiquitous use of PA by these plans, Reps. Suzan DelBene (D-Wash.), Mike Kelly (R-Pa.), Ami Bera, MD, (D-Calif.) and Larry Bucshon, MD, (R-Ind.) reintroduced the *Improving Seniors' Timely Access to Care Act of 2021* (HR 3173). If enacted, this bipartisan bill would:

- Establish an ePA program and require MA plans to adopt ePA capabilities;
- Require the Secretary of HHS to establish a list of items and services eligible for real-time decisions under an MA ePA program;
- Standardize and streamline the PA process for routinely approved items and services;
- Ensure PA requests are reviewed by qualified medical personnel;
- Increase transparency around MA PA requirements and their use; and
- Protect beneficiaries from any disruptions in care due to PA requirements as they transition between MA plans.

We believe that CMS can exercise its administrative authority to implement all of these proposed statutory reforms without additional legislation. With over half of the members of the House of Representatives as cosponsors and support from over 300 patient and provider organizations, the agency would be on sound footing to implement these changes to PA in the MA program.

¹³ Social Security Act (SSA) § 1852(a)(1)(A), (B).

Revisit Fail First Limits on Access to Part B Drugs Covered by MA Plans

In a 2012 guidance,¹⁴ CMS stated that MA plans must ensure beneficiaries have “at a minimum, equal access to items and services” covered in Medicare FFS. CMS added that coverage policies may not be more restrictive than FFS Medicare or impose extra barriers to Part B drug coverage, such as step therapy, that are not required in FFS Medicare. In August 2018, CMS rescinded its 2012 guidance and reversed its long-standing policy prohibiting MA plans from imposing step therapy for Part B covered drugs. CMS issued new guidance allowing step therapy in Medicare Advantage for physician-administered drugs, effective January 1, 2019.¹⁵

While we do appreciate that CMS included some safeguards intended to protect beneficiaries and ensure timely access to medically necessary Part B drugs in the final policy, those safeguards do not go far enough to protect patients. Therefore, we strongly recommend that CMS immediately reverse its decision to allow step therapy and reinstate the step therapy prohibition from its 2012 guidance.

We urge CMS to reinstate the ban on step therapy for Part B drugs covered by MA plans.

Implement e-Prior Authorization

As mentioned above, on December 10, 2020, CMS released a proposed rule titled “Reducing Provider and Patient Burden by Improving Prior Authorization Processes, and Promoting Patients’ Electronic Access to Health Information” (e-PA Proposed Rule). The e-PA Proposed Rule represented an important step forward in reducing the administrative burdens involved in PA while increasing transparency and included many of the reforms included in H.R 3173 and advanced by the RRC. However, the e-PA Proposed Rule failed to include MA plans, a concern raised in numerous [public comments](#).

The e-PA Final Rule is currently undergoing administrative review by CMS. We urge CMS to expand the scope of the requirements included in the e-PA Proposed Rule to MA plans and to publish the expanded e-PA Final Rule as soon as practicable.

Halt PA for Hospital Outpatient Services Under Medicare FFS

Given the clear consensus that the PA processes used by MA organizations need to be reformed, it is clearly inappropriate to extend these same processes to Medicare FFS. Yet, CMS has nevertheless promulgated rules applying PA requirements to hospital outpatient services provided to Medicare FFS beneficiaries.

The initial adoption of hospital outpatient PA requirements in the CY 2020 OPSS Final Rule (CMS-1717-FC) for five procedures¹⁶ constituted a significant departure from traditional Medicare claims processing practices. Nevertheless, before the agency and the Medicare Administrative Contractors (MACs) had an opportunity to assess this new system, effective July 1, 2021, CMS added two additional procedures to

¹⁴ Centers for Medicare & Medicaid Services. HPMS memo: “Prohibition on Imposing Mandatory Step Therapy for Access to Part B Drugs and Services.” September 2012. Available at: https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/hpmsmemosteptherapy_091712_13.pdf

¹⁵ Centers for Medicare & Medicaid Services. HPMS Memo: “Prior Authorization and Step Therapy for Part B Drugs in Medicare Advantage.” August 2018. Available at: https://www.cms.gov/Medicare/Health-Plans/HealthPlansGenInfo/Downloads/MA_Step_Therapy_HPMS_Memo_8_7_2018.pdf

¹⁶ Blepharoplasty, botulinum toxin injections, panniculectomy, rhinoplasty and vein ablation.

the list of hospital outpatient services subject to PA.¹⁷ While the hospital outpatient PA program ostensibly became fully operational over a year ago, as mentioned above, unacceptable delays continue, and physicians continue to experience significant challenges with these requirements.

We urge CMS to take the following actions:

- Immediately halt the PA requirements for the seven clinical areas currently subject to this new program. At the very least, CMS must closely monitor the implementation of the current PA requirements to ensure that decisions are made promptly and, if they are not, clarify that the PA requirements are not barriers to payment for these services;
- Release the MACs' PA data to improve transparency;
- Clarify the process for removing services from the PA requirements; and
- Suspend the use of PA for any additional services under all Medicare FFS programs.

Continue Delaying Implementation of the AUC Program for Advanced Diagnostic Imaging Services

Congress enacted the AUC Program for advanced diagnostic imaging services in response to a rapid rise in the utilization of certain diagnostic imaging services, such as MRI, CT and PET. The rapid rise in the utilization rate of these services has since abated. Furthermore, PAMA preceded the enactment of the Medicare Access and CHIP Reauthorization Act (MACRA), which included a value-based payment program for physician services. The AUC Program has been fraught with implementation challenges since its enactment and, in the intervening time, has grown outdated — particularly given MACRA and the rise of new health care payment and delivery models that hold clinicians responsible for health care resource use, such as alternative payment models, the Merit-based Incentive Payment System and Primary Cares Initiative.

Nevertheless, CMS is required by statute to implement the program, which sets up a complex exchange of information between clinicians that is not yet supported by interoperable electronic health record systems and that relies on claims-based reporting at a time when CMS is increasingly migrating away from claims-based quality reporting mechanisms. Furthermore, as previously mentioned, the type of decision support tools required to comply with AUC Program requirements may cost \$75,000 or more.

RRC members strongly support the provisions included in the 2022 Physician Fee Schedule Proposed Rule delaying further implementation of the AUC Program until January 1, 2023, or the January 1 following the end of the COVID-19 Public Health Emergency. And while we appreciate that CMS is once again delaying the enforcement of penalties, we continue to view the program as duplicative and unnecessary and support legislative and regulatory efforts to delay implementing the mandatory AUC consultation.

We also urge CMS to continue to examine the workability of the AUC Program as mandated by Congress. Since CMS has acknowledged on multiple occasions that the program is plagued by operational issues and other limitations for which it does not have solutions. These ongoing challenges recently caught the attention of Congress, resulting in language in the House Labor, Health and Human Service, Education Appropriations Subcommittee report adopted in July. The report includes the following provision:

Medicare Appropriate Use Criteria Program.

The Committee is aware that the Protecting Access to Medicare Act established the Medicare Appropriate Use Criteria (AUC) Program for advanced diagnostic imaging.

¹⁷ Implanted spinal neurostimulators and cervical fusion with disc removal.

While the Committee recognizes the value of encouraging physicians and other health care professionals to consult AUC and clinical guidelines to support medical decision making, more than seven years have passed since Congress created the AUC program, which has not advanced beyond educational and operations testing. The Committee requests a report within 180 days of enactment of this Act on implementation of this program, including challenges and successes. In this report, CMS shall consider existing quality improvement programs and relevant models authorized under Sec.1115A of the Social Security Act and their influence on encouraging appropriate use of advanced diagnostic imaging. The Committee directs CMS to consult with stakeholders, including medical professional societies and developers of AUC and clinical guidelines, when formulating its report.

We are optimistic this report language will result in a long-overdue discussion that will lead to legislation that repeals or substantially revises the law. Such action would give CMS and physicians the flexibility to consult AUC in a form and manner that is practical, efficient and meaningful to them and their practices. We also hope CMS will be responsive to the report language and work expeditiously to engage with AUC stakeholder organizations in formulating its report to Congress.

In light of the multiplicity of CMS utilization review programs and the potential barriers to care they create, the RRC urges CMS to initiate a broad review of these policies. We further request that the agency engages in active dialogue with the patient, provider and payer communities, and our Coalition looks forward to participating in that dialogue. To that end, we will follow up with your staff to identify a mutually convenient time to meet.

In the interim, if you have any questions, please do not hesitate to contact RRC's Regulatory Counsel, Diane Millman at Diane.Millman@PowersLaw.com.

Thank you for considering our request.

Respectfully,

American Academy of Family Physicians
American Academy of Neurology
American Academy of Ophthalmology
American Association of Neurological Surgeons
American Association of Orthopaedic Surgeons
American College of Surgeons
American Gastroenterological Association
American Osteopathic Association
Association for Clinical Oncology
Congress of Neurological Surgeons
North American Spine Society
Medical Group Management Association
Society for Cardiovascular Angiography and Interventions

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