Prior Authorization and Step Therapy Requirements Delay Medically Necessary Patient Care

Summary
Prior authorization (PA) is a burdensome and time consuming process that requires physicians to obtain pre-approval for medical treatments or tests before rendering care to their patients. Health insurers frequently require PA for pharmaceuticals, medical services and durable medical equipment. The Academy has heard from many ophthalmologists that Medicare Advantage (MA) plans, in particular, are increasingly imposing onerous PA requirements for medical services and procedures. These PA requirements delay or prevent access to necessary medical care and are particularly burdensome on physician practices, especially when the requests are ultimately approved in nearly all cases.

Step therapy, also known as “fail first,” is being utilized by health plans to determine coverage and requires patients to try and fail on the insurers’ preferred medications before covering the therapy prescribed by their health care provider. In August 2018, the Centers for Medicare & Medicaid Services (CMS) issued guidance allowing step therapy in Medicare Advantage (MA) for physician-administered drugs. The action reversed a long-standing policy that prohibited MA plans from using step therapy for Part B covered drugs unless also required in Medicare fee-for-service (FFS). At the time, CMS said this policy would give MA plans increased leverage to negotiate drug prices. The change took effect on January 1, 2019.

The Academy is spearheading a multi-pronged advocacy campaign to promote changes to a host of Medicare-related issues that are hurting ophthalmologists’ ability to provide quality patient care. Our efforts have focused on reducing prior authorization burdens in the MA program and getting CMS to revisit its 2018 step therapy guidance for MA plans.

Specifically, the Academy is supporting the Improving Seniors’ Timely Access to Care Act (HR 3173/S 3018). This bipartisan legislation seeks to address the lack of transparency, delays to patient care and physician burdens brought on by increased prior authorization usage under Medicare Advantage plans. This legislation is supported by nearly 300 members of the 117th Congress.

For step therapy, we have been partnering with nearly 60 physician and patient organizations to urge CMS to reinstate the step therapy prohibition in Medicare
Advantage plans for Part B drugs. To reimpose a step-therapy ban, CMS would likely have to include the change in a formal rule.

The Academy is also supporting the Safe Step Act (HR 2163/S 464) which would amend the Employee Retirement Income Security Act (ERISA) to require a group health plan (or health insurance coverage offered in connection with such a plan) to provide a robust exception process for step therapy protocols. While the legislation does not apply to Medicare beneficiaries, the Academy believes it would provide private patients with some of the basic protections from step therapy requirements.

**Request for Congress**
The Academy is asking members of Congress to co-sponsor the Improving Seniors Timely Access to Care Act to prevent delays in medically necessary care. We urge congressional leaders to pass this important legislation in 2022.

In addition, we are encouraging lawmakers to press the Department of Health and Human Services (HHS) to reverse CMS’ step therapy policy for Medicare Advantage plans and instead work with stakeholders to develop other solutions to lowering drug costs that won’t negatively impact timely access to much needed Part B treatments.

We also urge members of Congress to cosponsor the Safe Step Act to provide patients covered by group health plans with some of the basic protections from step therapy requirements.

**Background on Prior Authorization/Step Therapy Policies**

**Prior Authorization**
Health insurers frequently require prior authorization for pharmaceuticals, durable medical equipment and some medical services. The prior authorization approval process, now more than ever, consumes valuable physician and staff time, costs physician practices money, and may negatively impact patients by delaying much-needed treatment.

In 2018, the Academy surveyed more than 4,000 practicing ophthalmologists about prior authorization, and the survey results showed the significant burden that prior authorization policies can have on patients and physician practices. For the more than 400 survey respondents:

- 86% reported that prior authorization burdens have increased “significantly” over the past five years.
- 87% reported that care is “often” or “always” delayed for those patients whose treatment requires prior authorization.
- 89% reported that the prior authorization process can have a “significant” or “somewhat” negative impact on patients’ clinical outcomes.
- 89% reported that a stable patient was asked to switch from his/her medication by the insurer even though there was no medical reason to do so during the past five years.
- 94% described the burden associated with prior authorization as “high” or “extremely high.”
The American Medical Association (AMA) recently released results from its 2021 prior authorization physician survey which reaffirmed the results of the Academy’s earlier survey. The AMA survey of 1,000 practitioners confirms that prior authorization requirements delay patients’ access to medically necessary health care. This can be even more detrimental to patients during a public health emergency when patients with urgent medical conditions are seeking care. Key findings from the AMA survey include the following:

- Nine in 10 physicians (93%) reported that prior authorization programs have a negative impact on their patients’ clinical outcome.
- A significant majority of physicians (88%) said the burdens associated with prior authorization were high or extremely high.
- Medical practices complete an average of 41 prior authorizations per physician, per week, which consume the equivalent of two business days (13 hours) of physician and staff time.
- To keep up with the administrative burden, two out of five physicians (40%) employ staff members who work exclusively on tasks associated with prior authorization.

Prior Authorization under Medicare Advantage Plans

According to the most recently available CMS data, Medicare Advantage enrollment grew to nearly 44% of all beneficiaries by November 2021. That rate was about 33% five years ago. Medicare Advantage plans, sometimes called “MA plans,” are offered by private companies approved by Medicare.

Federal statute and CMS regulations explicitly require MA plans to provide coverage for all services covered under Medicare Parts A and B. The CMS Medicare Managed Care manual further provides that MA plans are “prohibited from implementing policies that are more restrictive than what is covered under Original Medicare.” However, physicians are reporting that MA plans have imposed increasingly onerous PA requirements that are more restrictive than Original Medicare. The Academy, and many other physician groups, believe that these prior authorization requirements are not appropriate under Medicare Advantage when a service would be covered if the patient were in Part B of fee-for-service (FFS) Medicare.

Ophthalmology Examples:

Treatments for Age-Related Macular Degeneration

- We have heard from retina specialists that some MA plans are requiring prior authorization for each intravitreal injection used to treat age-related macular degeneration (AMD), a chronic condition that requires monthly treatment.
- Other MA plans may require a prior authorization for the injections annually.
- We believe that requiring prior authorization for every treatment that a given patient will need for the rest of their life is excessive, especially since retina specialists report that MA plans are approving essentially 100% of their prior authorization requests for this service.
- In these instances, the monthly prior authorization requirement is an unnecessary impediment to the patient’s access to care rather than a check for true medical necessity.
Cataract Surgery

• Starting on July 1, 2021, Aetna implemented a new policy that requires prior authorization approval for all cataract surgery. This policy applies to all of Aetna’s lines of business, including MA plans, and all sites of service.
• This truly outlier policy is negatively impacting patients by delaying medically necessary care and placing significant new administrative burdens on physicians’ practices.
• This prior authorization policy has been implemented in such an inefficient manner that we estimate that tens of thousands of Aetna patients have experienced an unnecessary delay in cataract surgery since the policy was implemented in July 2021.
• Cataract surgery is vital to restoring patients’ vision and independence. It allows them to perform daily activities without fear of injuring themselves or having to rely on family members for assistance.
• Delaying care, as Aetna has done, can lead to adverse outcomes for patients. Cataracts reduce patients’ quality of life, interfere with their work, and puts them at increased risk of falls and car accidents.

Step Therapy in Medicare Advantage

In a 2012 guidance, 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 fee-for-service Medicare.

In August 2018, CMS rescinded the 2012 guidance and reversed its long-standing policy prohibiting MA plans from imposing step therapy for Part B covered drugs. CMS issued guidance allowing step therapy in Medicare Advantage for physician-administered drugs, effective Jan. 1, 2019. CMS said this new policy would give MA plans increased leverage to negotiate drug prices.

Although we do appreciate that CMS included some safeguards to protect beneficiaries and ensure timely access to medically necessary Part B drugs in its final policy, we do not believe those safeguards go far enough to protect patients. Consequently, the Academy has been urged CMS to reverse its 2018 decision to allow step therapy in the MA program and instead work with patients, physicians, and other key stakeholders to develop other solutions that will ensure Medicare beneficiaries continue to have timely access to the clinical treatments they need while lowering the cost of medications for patients and the Medicare program.

What the Academy Is Doing

The Academy is leading the multispecialty Regulatory Relief Coalition that is working to achieve these changes. Our partners include ophthalmic subspecialty groups, cardiology, neurosurgery, rheumatology, neurology, gastroenterology, orthopedic surgery, spine specialists, family physicians and the American College of Surgeons. We have been requesting that CMS provide oversight of the prior authorization requirements established by Medicare Advantage plans.

In the 117th Congress, our coalition also secured the introduction of bipartisan legislation, the Improving Seniors’ Timely Access to Care Act (HR 3173/S 3018). The
bill has received strong bipartisan support from nearly 300 members of Congress. Check to see if your lawmakers are supporting HR 3173 or S 3018.

For step therapy, we have been partnering with nearly 60 physician and patient organizations to urge CMS to reinstate the step therapy prohibition in MA plans for Part B drugs. To reimpose a step-therapy ban, CMS would likely have to include the change in a formal rule.

In the 117th Congress, we are also supporting the Safe Step Act (HR 2163/S 464) which would amend the Employee Retirement Income Security Act (ERISA) to require a group health plan (or health insurance coverage offered in connection with such a plan) to provide a robust exception process for step therapy protocols. The bill has received bipartisan support from nearly 150 members of Congress. Check to see if your lawmakers are supporting HR 2163 or S 464.

Congressional Action on Prior Authorization Reform
The Regulatory Relief Coalition secured the introduction of the Improving Seniors’ Timely Access to Care Act in the 117th Congress. We are working with Reps. Suzan DelBene, D-Wash.; Mike Kelly, R-Pa.; Ami Bera, MD, D-Calif.; Larry Buchson, MD, R-Ind.; and Sens. Roger Marshall, MD, R-Kan.; Kyrsten Sinema, D-Ariz.; and John Thune, R-S.D. to pass this important legislation.

This bipartisan legislation aims to increase transparency and streamline the prior authorization process in the Medicare Advantage program by:

- Establishing an electronic prior authorization (ePA) process and require MA plans to adopt ePA capabilities
- Requiring the Secretary of Health and Human Services to establish a list of items and services eligible for real-time decisions under an MA ePA program
- Standardizing and streamlining the prior authorization process for routinely approved items and services
- Ensuring prior authorization requests are reviewed by qualified medical personnel
- Increasing transparency around MA prior authorization requirements and their use
- Protecting beneficiaries from any disruptions in care due to prior authorization requirements as they transition between MA plans

Congressional Action on Step Therapy Reform
The Safe Step Act (HR 2163/S 464) was introduced by Reps. Raul Ruiz, MD, D-Calif.; Brad Wenstrup, DPM, R-Ohio; Lucy McBath, D-Ga.; Mariannette Miller-Meeks, MD, R-Iowa; and Sens. Lisa Murkowski, R-Ark.; Maggie Hassan, D-N.H.; Bill Cassidy, MD, R-La.; and Jackie Rosen (D-NV).

This bipartisan legislation would amend the Employee Retirement Income Security Act (ERISA) to require a group health plan (or health insurance coverage offered in connection with such a plan) to provide a robust exception process for step therapy protocols. Specifically, the legislation would require insurers to implement a clear and transparent process for a patient or physician to request an exception to a step
therapy protocol. Upon an exception request, insurers are required to reply within 24 hours for emergency requests, or within 72 hours for non-emergency exception requests.

The legislation would also require that group health plans grant an exemption if an application clearly demonstrates any of the following situations:

- A patient already tried and failed on the required drug.
- Delayed treatment will cause irreversible consequences.
- Required drug will harm the patient.
- Required drug will prevent a patient from working or fulfilling activities of daily living.
- Patient is stable on current medication.

What to Tell Congress

Prior Authorization

- Prior authorization (PA) is a burdensome process that requires physicians to obtain pre-approval for medical treatments or tests before rendering care to their patients.
- In recent years, physicians have found that Medicare Advantage plans have continued to impose an increasingly higher number of onerous prior authorization requirements.
- Share a story of how your practice and patients have been impacted (unnecessary delays in care) by prior authorization.
- The Improving Seniors’ Timely Access to Care Act (HR 3173/S 3018) seeks to address the lack of transparency, delays to patient care and physician burdens brought on by increased prior authorization usage under Medicare Advantage plans.
- More than 450 physician, provider and patient organizations have endorsed the legislation in the 117th Congress.
- This legislation was supported by nearly 300 members of Congress.
- Encourage your lawmakers to cosponsor the Improving Seniors’ Timely Access to Care Act if they haven’t already done so.
- Be sure to thank your representative if he/she supported the legislation in the 117th Congress.
- Also encourage your lawmakers to weigh in with their Congressional leaders to urge action on HR 3173/S 3018 in 2022.

Step Therapy:

- Ophthalmology patients with potentially blinding eye diseases are some of the most vulnerable patients in the Medicare program.
- For an ophthalmology patient, having to “fail first” on a MA plan’s preferred treatment option could result in permanent vision loss.
- Share a personal story of how step therapy requirements have negatively impacted one of your patients.
- Encourage your members of Congress to urge HHS to reverse CMS’ step therapy policy for Medicare Advantage plans and instead work with
stakeholders to develop other solutions to lowering drug costs that won’t negatively impact timely access to much needed Part B treatments.

- The Academy has prepared a draft letter that lawmakers can consider sending to the HHS Secretary urging action to protect Medicare Advantage patients from step therapy requirements.
- Urge your member of Congress to co-sponsor the Safe Step Act (HR 2163/S 464) if he/she has not already done so.
- Be sure to thank your lawmaker if he/she supported the legislation in the 117th Congress.