New Step Therapy Policy Threatens Medicare Advantage Patients’ Timely Access to Sight-Saving Treatments

ISSUE SUMMARY
In August 2018, the Centers for Medicare & Medicaid Services (CMS) issued new 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). CMS says this new policy will give MA plans increased leverage to negotiate drug prices. The change took effect on January 1, 2019.

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. Step therapy is already used by private commercial payers with questionable patient outcomes. But to adopt such a policy for nearly a third of Medicare’s patients is a major move that the Academy opposes. The Academy is working with a broad coalition of ophthalmology subspecialty groups, other physician organizations and patient advocacy groups to have CMS revisit its new step therapy guidance. We are exploring all available avenues to ensure that patients can continue to receive the care they require.

Request: The Academy encourages members of Congress to contact CMS and urge the agency to reverse its new step therapy policy and instead work with stakeholders to develop other solutions to lowering drug costs that won’t negatively impact timely access to needed care and avoids unnecessary vision loss.

BACKGROUND
One in every three people with Medicare is enrolled in Medicare Advantage (Medicare Part C). Medicare Advantage plans, sometimes called “MA Plans,” are offered by private companies approved by Medicare. Federal statute and regulations by the Centers for Medicare and Medicaid Services (CMS) explicitly require MA plans to provide coverage for all services covered under Medicare Parts A and B. 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 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In August 2018, CMS rescinded its 2012 guidance and reversed its long-standing policy prohibiting MA plans from imposing step therapy for Part B covered drugs.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. The new CMS guidance describes step therapy as a “type of prior authorization for drugs that begins medication for a medical condition with the most preferred drug therapy and progresses to other therapies only if necessary.”

Although CMS’ new step therapy policy states that step therapy can only be applied to new prescriptions and administrations of Part B drugs, the Academy has strong concerns that the agency’s guidance memo lacks sufficient patient protections to ensure that ongoing Part B
therapies cannot be disrupted and that beneficiaries currently receiving drugs cannot be forced to change their medication if they switch MA plans. The CMS memo also does not specify that it is the physician that will determine if a patient “fails” on the insurer’s preferred treatment option. Second eye treatments could also complicate the policy.

To date, the Academy is aware of several health plans that have implemented step therapy policies for ophthalmic drugs in 2019: Select Health Advantage, BCBS Blue Care Network of Michigan, Florida Hospital Care Advantage, Pacific Source Health Plan, Providence Health Plan and BCBS of North Carolina. While a small number of MA plans have instituted step therapy requirements in 2019, the Academy believes that additional plans will begin implementing step therapy requirements for their enrolled patients starting in 2020.

STEP THERAPY’S IMPACT ON PATIENTS AND PRACTICES

Patients’ Timely Access to Treatments:
Medicare beneficiaries receiving Part B covered drugs include some of the most vulnerable in the program – those with cancer, progressive blinding eye diseases, rheumatic diseases, multiple sclerosis, and compromised immune systems, among others. Requiring these beneficiaries to step through a plan selected drug regimen before accessing treatment recommended by their provider could have devastating consequences:

- Patients with cancer may have their cancer spread, risking complications or death.
- Patients with vision disorders could be at risk for irreversible blindness.
- Patients with multiple sclerosis could miss the window of opportunity to stop the progression of their illness before it becomes disabling.

Step therapy can lead to a critical delay in obtaining the medicines these patients need for the best outcome, potentially resulting in irreversible disease progression or death, complications, or hospitalizations, as well as increased costs for the Medicare program and its beneficiaries. Step therapy could be particularly challenging for very ill patients when they are least equipped to manage additional bureaucratic hurdles.

Impact on Ophthalmology Patients:
Currently, there are three anti-VEGF drugs used to treat eye diseases. Two of the drugs (Lucentis and Eylea) are FDA-approved and cost between $1,800-2,000 per injection. The third drug (Avastin) is used off-label and must be repackaged by a compounding facility. Avastin costs around $50 per injection.

These anti-VEGF drugs are not always interchangeable. For some retinal diseases, such as diabetic macular edema, there is growing evidence that Eylea and Lucentis provide better clinical outcomes than Avastin. The most appropriate course of treatment for a given medical condition depends on the patient’s unique clinical situation. The decision on whether to use an on-label, off-label or compounded medication must be a physician-patient decision.

Data from the Academy’s clinical data registry shows that Avastin is being used about 50 percent of the time. Clearly, physicians are using Avastin frequently, likely when medically appropriate for a patient. Forcing more frequent Avastin use could result in patients receiving a less-effective drug for their condition.

Physician-Patient Relationship:
While a drug or therapy might be generally considered appropriate for a condition, the presence of comorbidities, potential drug-drug interactions, or patient intolerances may necessitate the selection of an alternative drug as the first course of treatment. Step therapy requirements often fail to recognize such considerations, resulting in delays in getting patients the right treatment at the right time. A patient’s health care provider is in the best
position to assess their patients’ medical needs. Step therapy interferes with the physician-patient relationship as this practice often bypasses a recommended therapy from a health care provider to cut costs.

**Burdens on Physician Practices:**
Step therapy requirements can also be administratively burdensome on a physician and their staff. Physicians do not have ready access to patient benefit and formulary information. This lack of transparency makes it difficult to determine what treatments are preferred by a payor at the point of care and places practices at financial risk for the costs of administered drugs if claims are later denied for unmet (yet unknown) step therapy requirements. Furthermore, payor exemption and appeals processes can be complicated and lengthy, making them burdensome for busy physician practices and patients awaiting treatment.

Under the current proposal, there is no specific guidance the outlines a standardized step therapy process for physicians to adhere to. This lack of direction could increase administrative burden as physicians will have to navigate conflicting procedures to care for their patients. At a time when CMS has prioritized regulatory burden reduction in the patient-provider relationship, its new step therapy policy will add another layer of administrative burden on practices.

**Patient Protections:**
With the implementation of this new proposal, the Academy is concerned that there are not sufficient patient access protections in the new step therapy guidance, which could have a significant negative impact on patients with vision loss. There is currently no guidance from CMS that addresses:

- That it should be the physician who determines when a patient has failed on the insurer-recommended treatment;
- Clarifies that a patient who requires second eye treatment should be considered an established patient, and therefore, should not be subject to step therapy policies for that eye; and
- The criteria MA plans must follow to set up step therapy protocols.

**RECOMMENDATIONS**
The Academy strongly recommends that CMS reverse its decision to allow step therapy immediately and 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 TO TELL CONGRESS**

- 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 vision loss that cannot be restored.
- Share a personal story of how step therapy requirements in commercial plans have negatively impacted one of your patients.
- Encourage your members of Congress to contact CMS and urge the agency to reverse its new step therapy policy 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.