ASRS American Society of Retina Specialists

January 25, 2019

Seema Verma, MPH
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-4180-P, Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out-of-Pocket Expenses [CMS-4180-P]

Dear Ms. Verma,

On behalf of the American Society of Retina Specialists (ASRS), we submit the following comments in response to the Centers for Medicare & Medicaid Services (CMS) Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out-of-Pocket Expenses [CMS-4180-P] proposed rule, primarily regarding the proposal to allow plans to implement step therapy for Part B drugs in the Medicare Advantage (MA) Program. ASRS is the largest retina organization in the world, representing over 3,500 board certified ophthalmologists who have completed fellowship training in the medical and surgical treatment of retinal diseases. The mission of the ASRS is to provide a collegial open forum for education, to advance the understanding and treatment of vitreoretinal diseases, and to enhance the ability of its members to provide the highest quality of patient care.

Before providing specific comments and feedback on the proposed rule, we would like to initially express our deep disappointment that the Administration is reversing its longstanding policy to prohibit use of step therapy in MA, particularly while it seeks to decrease regulatory burdens for physicians through its Patients Over Paperwork initiative. In August 2018, CMS issued a memo ("2018 memo") to MA Organizations, "Prior Authorization and Step Therapy for Part B Drugs in Medicare Advantage," rescinding a September 17, 2012 memo ("2012 memo") that prohibited MA plans from using step therapy for Part B drugs. By reversing course on this prohibition, we are not only concerned about the loss of safeguards to the physician-patient relationship and significant patient protections, but the concomitant increase in administrative burden to physician practices as well as costs to both patients and physicians. While the agency acknowledges this burden in the proposed rule, it believes that the additional burden will be well worth the resultant cost savings to the Medicare program from implementing step therapy. We are not convinced. Nor do we believe it is appropriate to attempt to lower the cost of prescription drugs by imposing the burden on physicians and preventing patients from receiving sight-saving therapies instead of trying to limit the cost of pharmaceuticals directly with drug manufacturers.

ASRS opposes step-therapy protocols that require patients to fail certain treatments before allowing access to other, potentially more appropriate treatments. The most appropriate course of treatment for a given medical condition depends on the patient's unique clinical situation. While a particular drug or therapy might be generally considered appropriate for a condition, the presence of comorbidities, potential drug-drug interactions, or patient intolerances, for example, may necessitate the selection of an alternative drug as the first course of treatment. Step-therapy requirements interfere with medical decision-making and often delay patients receiving the most appropriate treatment in a timely manner. Studies have shown that delaying the start of an appropriate medication may result in suboptimal treatment response even though the drugs are switched at a later date. For some patients with progressive blinding eye disease, this could result in unrecoverable sight loss.

As part of the Alliance of Specialty Medicine, through a separate coalition of specialties vigorously opposing step therapy, and with the American Medical Association and other specialty organizations, ASRS has stated its strong opposition to the policy change in the 2018 memo - not only because the proposal unlawfully created new

20 North Wacker Drive
Suite 2030
Chicago, IL 60606

phone 312 578 8760
fax 312 578 8763
www.asrs.org

substantive policy outside of the rulemaking process, but mainly because of the reasons set forth above.[1] Further, our coalition presented arguments that the policy, even if promulgated through rulemaking, is unlawful under Medicare law. We urged the Administration to leave in place the prohibition on step therapy for Part B drugs in MA.[2]

Despite our urging, the Administration now proposes to codify the 2018 memo in this regulation entitled "Medicare Advantage and Step Therapy for Part B Drugs," perhaps resolving one legal issue, but not the other. ASRS continues to believe that implementation of a step therapy program is a violation of §§ 1852(a)(1)(A) and (a)(B)(1) of the Social Security Act, which require that MA plans "provide to members enrolled under [Medicare Advantage] . . . benefits under the original Medicare fee-for-service program option," and which define these benefits as "those items and services… for which benefits are available under parts A and B." Implementation also violates the regulations at 42 C.F.R. §§ 417.414(b) and 422.101(a)-(b), which require MA plans to "provide coverage of . . . all services that are covered by Part A and Part B of Medicare . . . and that are available to beneficiaries residing in the plan's service area."

As CMS notes in the proposed rule, it had prohibited MA plans from using step therapy for Part B drugs because "such a utilization management tool would create an unreasonable barrier to coverage of and access to Part B benefits[.]" Despite this barrier, CMS touts the potential costs savings that utilization management tools can provide so that MA plans can better manage and negotiate the costs of providing Part B drugs. CMS is proposing to allow the use of step therapy for Part B drugs in MA, effectively prioritizing cost over beneficiary access, in an effort to address the high cost of prescription drugs. Nonetheless, the concern and reality that step therapy is an "unreasonable barrier" to coverage and access remains. **We continue to oppose allowing MA plans to use step therapy protocols for Part B drugs and we urge CMS to withdraw the proposal as it is in violation of the Medicare statute. If CMS finalizes the proposal, we urge it to ensure stronger safeguards than those proposed.**

Medicare Advantage and Step Therapy for Part B Drugs

In the proposed rule, CMS proposes to define step therapy as "a utilization management policy for coverage of drugs that begins medication for a medical condition with the most preferred *or* cost-effective drug therapy and progresses to other drug therapies if medically necessary." [Emphasis added.] We object to this definition because step therapy is not a utilization management tool, but a coverage tool. CMS appears to define it as such to circumvent the Medicare statutory prohibition we note previously. Further, it allows MA plans to require a particular drug solely based upon cost. Only drugs that have a therapeutic advantage in terms of safety and efficacy should be required as a part of a step therapy program.

We do appreciate that CMS proposes shortened timeframes for MA plans to make medically necessary determinations and for appeals of those determinations, however, it is critical that any request for direct access to a Part B drug that would otherwise only be available after trying an alternative drug is addressed as promptly as possible and based on appropriate medical necessity criteria. Unlike Part D drugs, Part B drugs are almost exclusively administered to the sickest patients, are required to be administered by a healthcare professional, and, therefore, require a patient to go to their doctor to receive treatment. Thus, there is the additional complicating factor for Part B drugs that physician offices need to schedule patients to receive the treatment. **For this reason, MA plans should be required to make all decisions about Part B drugs within a 24-hour timeframe.**

[1] Alliance letter to Seema Verma re August 2018 Memo (Sept. 2018); AMA and Specialty letter to Seema Verma, Administrator, re Memo of August 7th Regarding Prior Authorization and Step Therapy for Part B Drugs in Medicare Advantage (Sept. 7, 2018).
[2] Letter Demetrios Kouzoukas, Principal Deputy Administrator & Director of the Center for Medicare, re August 7, 2018 Step Therapy Memorandum (Dec. 31, 2018).

Further, although CMS indicates that it monitors organization determination and appeals activity through the audit process to ensure enrollee requests are appropriately evaluated and processed, we have some concerns and suggestions which we note below.

Safeguards

CMS proposes a number of safeguards to alleviate access concerns, however ASRS believes they would be insufficient to prevent barriers to beneficiary access from becoming a reality. Our members experiences with some commercial insurer step therapy plans which make it very difficult to change therapy in a patient who is failing the initial treatment. First, CMS proposes to take existing processes and procedures used in Part D and apply them to Part B despite the fact that healthcare providers find the current procedures lacking. CMS proposes, for example, an appeals process similar to the current process under Part D despite significant challenges with the Part D exceptions process noted by healthcare providers. In 2017, the Medicare Payment Advisory Commission (MedPAC) reported that "[b]eneficiary advocates, prescribers, plan sponsors, and CMS have all noted frustrations with Part D coverage determinations, exceptions, and appeals processes" and recommended resolving issues "at the point of prescribing through e-prescribing and electronic prior authorization rather than at the pharmacy counter." (Chapter 14, Report to the Congress: Medicare Payment Policy March 2017)

Further, during the MedPAC October 2017 meeting discussing the March report, staff noted that "CMS has found that several plan sponsors fail to comply with regulations in areas such as formulary requirements, coverage determinations, and exceptions and appeals processes." If plans are not complying with them, even improved protections would fail to be of any use. **We urge the Administration to make improvements to the Part D exceptions and appeals process and enforcement and oversight of such requirements before replicating this system in Part B to ensure fair and expeditious processes ensure full compliance by plan sponsors.**

Similarly, CMS proposes that the existing Part D requirements regarding use of Pharmacy & Therapeutics (P&T) Committees be applied to Part B step therapy requirements, yet many specialists believe these committees are often not sufficient to protect beneficiaries who suffer from conditions requiring specialty or subspecialty care. For example, a six-person P&T Committee would satisfy CMS' requirements if it consists of 4 practicing pharmacists, 1 additional practicing pharmacist who is an expert "in the care of elderly and disabled persons," and 1 practicing family care physician. While these individuals undoubtedly bring critical expertise, they should not make coverage decisions for beneficiaries suffering from retinal diseases and blinding eye conditions. **Given the severity of conditions that are treated by retina specialists with Part B drugs, we urge CMS to create more stringent requirements around P&T Committee membership that requires inclusion of specialists and subspecialists who treat conditions prevalent in the Medicare population.**

Under the proposal, MA plans must follow existing disclosure requirements when applying step therapy to Part B drugs, must disclose that Part B drugs "may be subject to step therapy requirements" in the Annual Notice of Change (ANOC) and Evidence of Coverage (EOC) documents, and must establish policies and procedures to educate and fully inform contracted health care providers concerning policies on utilization management, including step therapy. If our experience with prior authorization policies is demonstrative, these existing requirements are not enough. Despite these requirements, MA plans are overusing and misusing prior authorization practices because CMS has not provided adequate guidance on what constitutes appropriate prior authorization, nor does the agency in its oversight role collect adequate data to assess the utility of these programs and their impact on patient access to care. Further, physicians do not have ready access to patient benefit and formulary information, as there is currently no capability making this information available through electronic health records or other means at the point of prescribing. This lack of transparency makes it exceedingly difficult to determine what treatments are preferred by a particular payor at the point of care and places practices at financial risk for the cost of Part B drugs if claims are later denied for unmet (unknown) step therapy requirements.

CMS proposes to also include a requirement for plans to establish policies and procedures to educate and inform health care providers and enrollees specifically concerning its step therapy policies. **We appreciate this additional requirement and we urge CMS to issue sub-regulatory guidance specifying the detail that must be provided not only in the education materials but in the ANOC and EOC documents as well, and that changes must not be made mid-year. Further, we urge CMS to collect adequate data to assess the utility of these programs and monitor and report on their impact on patient access to care**.

Exemptions

ASRS appreciates that the proposed rule provides that "step therapy would not be permitted to disrupt enrollees' ongoing Part B drug therapies" as it would only apply to "new administrations" of Part B drugs utilizing a look-back period of at least 108 days. The preamble notes that this would mean that patients "actively taking" a Part B drug would be exempt. We appreciate this explicit parameter and we urge CMS to ensure this would include active treatment for new enrollees, whether under prior plans, are new to Medicare or patients who began a therapy in an acute care setting and have been discharged for treatment in the community.

CMS proposes that MA plans have flexibility in implementing step therapy for Part B drugs within specific parameters. Specifically, MA plans would be able to ensure that an enrollee who is newly diagnosed with a particular condition would begin treatment with a cost-effective biological product approved under section 351(k) of the Public Health Service Act or generic medication before progressing to a more expensive drug therapy if the initial treatment is ineffective or if there are adverse effects. The proposal does not specifically address the standard for exemptions or movement within a step therapy program, but "rel[ies] on the MA plan's responsibility to provide all medically necessary covered services and items under the original Medicare program as meaning that cases raising ineffectiveness or adverse effects of treatment as being sufficient basis to grant an exemption or move an enrollee to a higher step in the protocol." CMS notes that the only limits it proposed are for off-label and non-covered drugs.

Although CMS is not proposing specific requirements, CMS states that an MA organization may establish an evaluation process for the appropriateness of enforcing its step therapy protocols on an enrollee when the enrollee's healthcare provider's assessment of medical necessity for the Part B drug indicates that the lower or earlier steps in the step therapy protocol are not clinically appropriate for that enrollee (such as in cases of allergy or a prior unsuccessful use of the preferred drug). CMS explains that MA organizations may work with their network providers to develop processes that eliminate the necessity for an enrollee to file a request for an organization determination in such cases. **Rather than suggesting such actions, we urge CMS to make it a requirement that plans develop such processes. Specifically, plans should work in conjunction with network physicians to establish processes that would allow certain enrollees to be exempt, either automatically and/or on a case-by-case basis, from step therapy requirements.**

Off-Label Indications

CMS proposes to permit MA plans to require an enrollee to try and fail an off-label medically-accepted indication only if it is supported by one or more citations in the statutory compendia before providing access to a drug for an FDA-approved indication (on-label indication). As mentioned previously, ASRS opposes step-therapy protocols that require patients to try and fail certain treatments before allowing access to potentially more appropriate treatments. We are particularly concerned about step-therapy policies that require the off-label use of Avastin when FDA-approved drugs (Eylea® and Lucentis®) are available as it undermines the authority of the Food and Drug Administration.

Although ASRS and retina specialists have fought hard to preserve access to Avastin we have several concerns with an Avastin-first requirement. It is well-established that pharmaceutical manufacturers are prohibited from

proactively communicating about off-label indications of their products. We are concerned that allowing a party with a financial interest (the insurer) to require patients to use an indication that has not been found safe and efficacious by the Food and Drug Administration runs afoul of the spirit underlying the restrictions on off-label communications. While the insurer must rely on statutory compendia and will likely have its own data supporting the off-label use, this falls short of the clinical data required for a finding of safety and efficacy by FDA. We urge CMS not to empower insurers to use financial incentives and disincentives to require patients to use a product for an indication that is not FDA-approved. These decisions should remain firmly with the physician and the patient.

While lower-cost Avastin can be effective for some patients and is often used by retina specialists, we believe that physician choice is essential to treating retinal diseases. We urge CMS to prohibit plans from implementing any policy that is not based on sound clinical and scientific evidence for diabetic macular edema and age-related macular degeneration. There are several safety issues may affect intravitreal therapy choices and the most appropriate course of treatment depends on the patient's unique clinical situation. As stated previously, step-therapy requirements interfere with medical decision-making and often delay getting patients the right treatment at the right time. For some retina patients, this could result in unrecoverable sight loss.

Conclusion

In sum, ASRS strongly opposes step therapy policies and we oppose this proposal to permit MA plans to implement step therapy for Part B drugs. Step therapy is a coverage tool that, if used by MA plans, will inappropriately deny Medicare beneficiaries access to Part B items and services that they would receive under Original Medicare, it will delay access to necessary care, and will interfere with physician decision-making and the physician-patient relationship. We believe the Medicare statute precludes CMS from permitting MA plans to impose step therapy on Part B drugs and urge CMS to not finalize this rule. Should CMS finalize this rule, it is imperative that the changes we recommend be implemented to protect patients and ensure access to covered Part B drugs.

Further, if this rule is finalized, ASRS and the Alliance would appreciate the opportunity to meet with agency officials from the Oversight and Enforcement Group, as well as those responsible for the Quality Ratings System (QRS) to discuss establishing a feedback loop whereby specialty physicians can share information when plans are not adhering to step therapy requirements. In addition, we would like to discuss ways to potentially leverage the QRS/Stars Rating program to hold plans accountable for ensuring enrollees are receiving medically necessary specialty care and any required medicines as part of a treatment protocol, in a medically appropriate timeframe.

Please do not hesitate to contact Jill Blim at Jill.Blim@asrs.org if you have any questions. We appreciate your consideration of this request.

Sincerely,

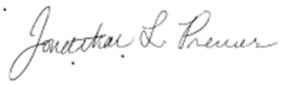
John S. Pollack, MD
President

Timothy G. Murray, MD, MBA
President-Elect

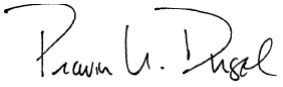
Carl C. Awh, MD
Program Chair

Philip J. Ferrone, MD
Chair, Council on Governance

Judy E. Kim, MD
Treasurer

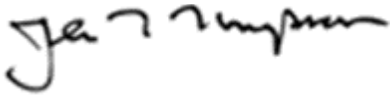


Jonathan Prenner, MD
Secretary



Chair, Council on Education
Pravin Dugel, MD

Immediate Past President
Mark S. Humayun, MD, PhD



Chair, Council Health Economics
John T. Thompson, MD

APPENDIX A

ANALYSIS OF PRACTICE REVENUES AND EXPENSES FOR DRUGS ADMINISTERED IN RETINA PHYSICIAN OFFICES

BACKGROUND

On March 8, 2016, the Centers for Medicare & Medicaid Services (CMS) announced a proposed rule to test new models to improve how Medicare Part B pays for prescription drugs and supports physicians and other clinicians in delivering higher quality care.

Currently, Medicare Part B covers prescription drugs that are administered in a physician's office or hospital outpatient department, such as cancer medications, injectables like antibiotics, or eye care treatments. Drugs paid under Medicare Part B generally fall into three categories:

1) Drugs furnished incident to a physician's service in the office or hospital outpatient settings,
2) Drugs administered via a covered item of durable medical equipment, and
3) Other categories of drugs explicitly identified in the law.

PROPOSED RULE AND CHANGES IN PAYMENT THAT WOULD APPLY TO OPHTHALMIC DRUGS ADMINISTERED BY RETINA PHYSICIANS

Medicare Part B generally pays physicians and hospital outpatient departments the average sales price of a drug, plus a 6 percent add-on. The proposed model would test whether changing the add-on payment to 2.5 percent plus a flat fee payment of $16.80 per drug per day changes prescribing incentives and leads to improved quality and value. CMS goes on to say that:

> "CMS expects that the add-on payment of 2.5 percent plus a flat $16.80 fee will cover the cost of any drug paid under Medicare Part B. The flat fee is calculated such that it is budget neutral in aggregate."

While the proposal may be budget neutral in aggregate, the fact is that CMS does not know the impact of specific subspecialties based on provider financials, treatment mix, and so forth.

Therefore, the American Society of Retina Specialists (ASRS) commissioned an independent study by an economics and accounting firm, Quorum Consulting, Inc. (San Francisco, CA) to gather data from retina practices to: (1) determine revenue for injectable drugs; (2) account for direct and indirect costs associated with injectable drugs; in order to: (3) report profit or loss for physician administered drugs that may be affected by the proposed rule.

ABSTRACT OF STUDY METHODS AND RESULTS

Methods

We solicited members of the ASRS to provide detailed financial and cost accounting data. We requested data on revenues (total collections) and costs (expenses) for calendar year 2015. We obtained data on all injectable drugs administered retina physician practices offices (hospital and ASC facilities were not included). The scope of the analysis was specific to FDA approved drugs with product specific HCPCS "J" codes, which are addressed within the scope of the CMS proposal.

Cost Accounting Data Collection

For direct and indirect expenses, we obtained site-specific data on:

Drug Acquisition Costs (by HCPCS code)

a. Acquisition price per unit
b. Added costs
    a. Shipping and handling
    b. Sales tax
    c. Other cost increases
c. Cost offsets
    a. Discounts
    b. Chargebacks
    c. Rebates
    d. Other cost offsets

Other Practice Expenses

a. Practice Expenses
b. Staff Time
    - Salaries and benefits for staff time responsible for acquiring, storing, preparing, transporting, disposing of drugs and drug revenue collections * this differs from GAO allocated based on time spent on these activities
c. Other indirect expenses
    - Space - Physical space used for storing and preparing drugs
    - Equipment - Equipment used for storing, preparing, transporting, disposing of drugs and claims management (office equipment, PODIS, EHR, other IT, etc.)
    - Supplies - Supplies used for storing, preparing, transporting, and disposing of drugs
    - Support Contracts - Contracts for other organizations to provide services supporting acquiring, storing, preparing, transporting, and disposing of drugs (e.g. waste disposal)
    - State provider taxes

Results and Discussion

We obtained detailed revenue (collections) and expenses (direct and indirect costs) for calendar year 2015 from 8 retina practices from around the country. While sites were from regions throughout the country, participating sites all tended to be high volume practices. This is likely due to the fact that sites had to provide data in a short amount of time (to accommodate the CMS comment period), and only high volume sites had accounting and other administrative staff available to provide the requested information. Participating sites also varied in their payer mix and utilization of different types of drugs.

We found that drug acquisition and overhead expenses for injectable drugs included in the analysis were on average 98.9% (range 96.5% to 103.2%) of total collections across the 8 practices. In some cases, practices made a profit on injectable drugs while in other cases had a net loss. There was variation in drug profit or loss by drug and by practice.

It is worth noting that given the limited time available to collect these data, only high volume practices with capable financial staff were able to respond to the survey in this short period of time. Even under these circumstances, not all high volume practices generated profits on office administered drugs. In fact, our belief is

that lower volume practices, which provide the majority of patient care in retina around the country would have less purchasing power and higher overhead compared to the study for which we were able to collect data.