BY ELECTRONIC DELIVERY

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

Dear Administrator Verma:

On behalf of the National Infusion Center Association (NICA), the hundreds of thousands of patients across the nation requiring provider-administered parenteral medications, and the infusion providers that treat them, I am pleased to submit comments in response to the Administration’s proposed rule (CMS-4180-P) relating to modernizing Medicare Advantage to lower drug prices and reduce out-of-pocket expenses.

NICA is a 501(c)(3) nonprofit patient advocacy organization formed to ensure that our nation’s sickest and most vulnerable patients can access in-office infusion and injectable medications through advocacy, education, and resource development. We represent hundreds of thousands of patients managing complex, chronic diseases, including autoimmune diseases, with medical benefit drugs.

There are many complex, multi-faceted challenges facing the sustainability of our health care system. Autoimmune diseases have high economic burden of disease and the specialty medications used to manage these conditions—particularly biological products—are incredibly expensive and list prices for these drugs continue to increase, translating to increased out-of-pocket (OOP) costs for patients and increased cost burden on payers. Payers in the commercial space have been leveraging utilization management strategies, like prior authorization and step therapy, to increase their negotiation leverage with pharmaceutical manufacturers in an effort to minimize cost-burden and control utilization of high-cost drugs, like biologics.

Unfortunately, these utilization management strategies have delayed, restricted, and disrupted access to care for many patients, translating into increased consumption of high-cost, non-drug health care services, increased out-of-pocket expenses, poorer health outcomes, reduce quality of life, and increased long-term cost burden on the payer.

NICA appreciates CMS’ efforts to reduce Medicare program expenditures, provide Medicare Advantage plans with tools to negotiate lower drug costs, and reduce beneficiary out-of-pocket costs. However, we are concerned that the proposed policy changes disproportionately favor health plans instead of focusing on beneficiary protections, ultimately to the detriment of patients.
NICA submits comments to bring the following concerns to the administration’s attention:

- Step therapy is inappropriate for Part B drugs and may cause restrictions, delays, and disruptions in care with adverse clinical and financial implications; and,
- The proposed rule lacks adequate and appropriate beneficiary protections and safeguards.

**Step therapy is inappropriate for Part B drugs and may cause restrictions, delays, and disruptions in care with adverse clinical and financial implications.**

NICA supports the administration’s goals to reduce cost across the Medicare program while ensuring access to medically necessary Medicare-covered benefits. Medicare Advantage (MA) plans need to have tools at their disposal to control unnecessary utilization of medical benefit drugs and manage overall costs. However, there is great concern that permitting the application of step therapy in Medicare Advantage plans for Part B drugs may not achieve these goals and rather produce unintended consequences. Particularly, in the absence of strong safeguards to ensure beneficiaries are protected.

NICA opposes insurer practices to intervene in the patient-physician relationship, supersede the prescribing authority of the prescriber, and dictate a treatment protocol for patients. As such, NICA opposes step therapy for biologics and other provider-administered intravenous/injectable drugs because these policies have the potential to produce poorer health outcomes, reduce quality of life, unnecessarily increase health care consumption, and increase costs.

Biological products are used to manage some of the most expensive conditions (e.g., autoimmune diseases, cancer), for which patients are subjected to extraordinary economic burden of disease and high OOP costs. It can take months or years to find the right medication, achieve disease remission, and minimize the economic burden of disease. When access to these medications is restricted, delayed or disrupted, the economic burden of disease increases as more health care services are consumed to manage symptoms of disease. For some medications, step therapy—or “fail first” policies—may be reasonable; such as when the clinical risk is low, the time to fail is short, and the cost to fail is low. However, for biologics and most medical benefit drugs, step therapy is inappropriate because the clinical risk is high, the time to fail is long and the cost to fail is high.

**Step therapy is inappropriate when the time to fail is long.** Biologics, and many intravenous and injectable medications, require a long time to be trialed and documented for failure. It can take months to “fail” on “preferred biologics” listed by many commercial health plans. For a patient with progressive chronic disease, this time equates to poorer health outcomes, increased economic burden of disease, and significantly reduced quality of life. Requiring a patient to trial what might be an ineffective or second-choice biologic—as determined by the prescriber and patient—can allow further progression of disease to a state that requires otherwise avoidable consumption of high-cost health care services.

**Step therapy is inappropriate when clinical risk is high.** All medications, including many health plan-defined “preferred biologics”, carry an inherent clinical risk that varies between patients. Many biologics carry FDA Black Box warnings and adverse event profiles that are far from benign (e.g., serious infections, malignancies, and injection site reactions). NICA believes it is the primary responsibility of the prescriber and patient, not the health plan, to weigh these clinical risks and make a collaborative decision as to which medication is the most appropriate. It is inappropriate for a health plan to make this decision and subject the patient to the additional clinical risk associated with an insurer-preferred medication. **Beneficiaries should not be required to expose themselves to these unnecessary clinical risks prior to receiving the provider-prescribed treatment they need.**
Step therapy is inappropriate when the cost to fail is high. Many drugs covered under Part B cost thousands of dollars per treatment with a long-term treatment duration. It can take months to document failure, so the cost of trying and failing the wrong drug can be significant. The more steps, the greater the cost burden for both beneficiary and payer. Everyone loses when a beneficiary receives thousands of dollars worth of medication without therapeutic benefit, more so if disease progression occurs as a result.

In theory, step therapy may increase insurers’ leverage to reduce drug costs. In practice, however, step therapy has evolved into a tool to reduce payer costs by forcing patients to try insurer-preferred medications before provider-prescribed medications will be covered, often to the detriment of patients. Essentially, step therapy is allowing insurers to practice medicine. The clinical and financial implications of step therapy can be severe and heavily outweigh any cost-savings realized in the short-term. Permitting the application of step therapy by Medicare Advantage plans for drugs covered under Part B will significantly weaken beneficiary protections with the potential to delay effective management of complex, chronic disease resulting in increased economic burden of disease, increased out-of-pocket costs for beneficiaries, poorer health outcomes, reduced quality of life, and increased cost burden on Medicare.

The proposed rule lacks adequate and appropriate beneficiary protections and safeguards.

Again, NICA supports the administration’s goals to reduce cost across the Medicare program while ensuring access to medically necessary Medicare-covered benefits, but we oppose the application of step therapy for Part B drugs. If the administration proceeds with the proposed rule to permit the application of step therapy in MA plans for Part B drugs, strong safeguards should be put in place to protect beneficiaries while ensuring access the medically necessary Medicare-covered benefits. In the absence of strong safeguards, NICA is concerned that step therapy in MA plans will unnecessarily subject beneficiaries to harm by increasing clinical risk, increasing cost, and delaying access to effective therapy.

Specifically, NICA believes that the following guardrails should be established:

- Step therapy requirements must not increase beneficiaries’ out-of-pocket costs or clinical risk (e.g., immunogenicity);
- Step therapy requirements must not be discriminatory (e.g., specific to a disease state or specialty);
- Step therapy guidelines must align with clinical guidelines and be supported by clinical evidence;
- Step therapy requirements must not step across benefit plans (i.e., Part D drug before Part B drug or vice versa);
- MA plans utilizing step therapy policies must be transparently denoted and displayed on the MA plan finder portal;
- A transparent and expeditious exception process should exist, like those that many states are establishing in statute, with a mandatory response time of 72-hours, or 24-hours in the case of a medical emergency;
- “Look-back” periods must be consistent with clinical guidelines and appropriate for the beneficiary’s condition(s), so patients that have completed step therapy requirements are not subjected to the same step therapy requirements again in order to restart therapy; and,
- Protections must be in place for beneficiaries that become “new” patients after the “look-back” period (i.e., complied with step therapy requirements, but discontinued therapy for ≥108 days and are seeking to restart therapy).
Conclusion

There are many complex, multi-faceted challenges facing the sustainability of our health care system. As the cost of expensive biologics and other specialty medications continue to increase, it is important to explore strategies to reduce unnecessary consumption of these high-cost drugs and mitigate Medicare’s cost burden, while preserving access to these medications for those that desperately need them.

Medicare reform should first and foremost be focused on preserving, optimizing, and expanding beneficiaries’ access to care. Patients rely on uninterrupted access to prescribed therapies to manage their conditions, reduce consumption of high-cost health care services, minimize the economic burden of disease, and maximize quality of life.

NICA, CMS, advocacy groups, providers, and health plans share a similar view—to decrease patient suffering, improve health outcomes, and optimize quality of life as safely and economically responsible as possible. However, forcing Medicare beneficiaries to fail thousands of dollars worth of medications without therapeutic benefit is an all-lose proposition. Therefore, NICA finds it impractical, wasteful, potentially harmful—and, therefore, unethical—that accessing provider-prescribed medications would require failing one or more insurer-preferred medications.

NICA applauds the administration’s ongoing commitment to addressing the rising cost of drugs and patient out-of-pocket costs. We share and support the administration’s commitment, so long as reform measures do not interrupt, restrict, or delay access to care. Due to our concern that the application of step therapy in Medicare Advantage plans for Part B drugs will prevent patients from receiving the right care at the right time, we implore the administration to prohibit the use of step therapy policies in MA plans for Part B drugs.

If the administration decides to move forward and allow step therapy in MA plans for Part B drugs, we would urge the administration to establish guardrails and strong beneficiary protections to ensure that beneficiaries will not be inappropriately subjected to increased clinical risk, increased costs, and increased economic burden of disease. Additionally, we would implore CMS to establish a transparent and expeditious exception process through which providers can receive an exemption from step therapy requirements if a patient may experience increased clinical risk, increased potential for harm, increased cost, or increased economic burden of disease.

Thank you for the opportunity to submit comments on this proposed rule. NICA would welcome the opportunity to serve as a resource in ensuring that beneficiaries can get the right care at the right time for the lowest cost and minimize the economic burden of disease.

Should you have any questions or need more information, please feel free to contact me at brian.nyquist@infusioncenter.org or 512-402-6955.

Sincerely,

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Executive Director
National Infusion Center Association