19176 Hall Rd, Ste 130
Clinton Twp, MI 48038
autoimmune.org

April 14, 2023

Meena Seshamani, M.D., Ph.D.
CMS Deputy Administrator and Director of the Center for Medicare
Centers for Medicare & Medicaid Services
U.S. Department of Health & Human Services
7500 Security Boulevard
Baltimore, Maryland 21244-1850

Re: Medicare Drug Price Negotiation Program Guidance: Initial Memorandum, Implementation of Section 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2026, and Solicitation of Comments

Dear Administrator Seshamani,

As the world's leading nonprofit organization dedicated to autoimmune disease advocacy, awareness, education, and research, the Autoimmune Association appreciates the opportunity to respond to the Centers for Medicare and Medicaid Services' initial draft guidance detailing the requirements and parameters for the new Medicare Drug Negotiation Program.

People living with autoimmune diseases face unique challenges in their day-to-day lives and depend on novel and innovative treatments to successfully manage their conditions. The Inflation Reduction Act's drug pricing provisions will have wide-ranging implications for not only Medicare beneficiaries, but all autoimmune patients who stand to benefit from innovative therapies that are currently on the market, as well as those in the development pipeline.

As the agency moves to implement this and future program guidance, we urge policymakers to remain vigilant of potential unintended consequences that could jeopardize future patient access to these therapies.

We would like to call your attention to the following components of the draft guidance which are of particular concern to us.

The Medicare Drug Price Negotiation Program should consider patient access beyond coverage requirements.

Coverage is only one component of access. As an organization dedicated to advancing policies that improve the heath and well-being of people living with autoimmune disease, the Autoimmune Association is particularly attuned to the impacts of payer-imposed access barriers on patients. Though our Let My Doctors Decide initiative, we recently rolled out a national scorecard assessing the extent to which insurers – including Medicare Advantage and Part D prescription drug plans – and their pharmacy benefit managers restrict access to medications to manage some of the most common autoimmune diseases affecting an estimated 15.9 million Americans.[1] The scorecard looked at three types of utilization management tactics employed by payers: step therapy, prior authorization, and restrictive formulary placement.

The results were not promising. Few – if any – plan types received a "A' grade under our criteria. Across all conditions, nearly half of all Medicare Advantage and Part D plans achieved a failing score and nearly 9 in 10 plans scored a C or worse.

With close to half of all Medicare beneficiaries now enrolled in a Medicare Advantage plan, and approximately 47% enrolled in a standalone Part D plan, changes to how the Medicare program pays for prescription drugs will have major implications for this subset of the Medicare population.

[1] Health Insurance Access Barriers: A National Scorecard. January 2023. Let My Doctors Decide. Accessed: https://autoimmune.org/healthplanscorecard/

As it implements this and future guidance, we encourage CMS to consider the impact of payer benefit design on patient access in addition to requiring coverage for treatments within the Drug Price Negotiation Program.

CMS definition of "unmet medical need" is too narrow

In section 1194(e)(2) of the IRA legislation, CMS is required to consider the extent to which a drug fulfills an "unmet medical need" as part of the negotiation process. However, in the guidance, CMS states its intention to define unmet medical need as treating "a disease or condition in cases where ***very limited or no other treatment options exist***."

We believe CMS' interpretation of unmet medical need is too narrow and may not be entirely consistent with how it is referenced in 1194(e)(2): "The extent to which the
selected drug and the therapeutic alternative to the drug address unmet medical needs for a condition for which treatment or diagnosis is not addressed ***adequately*** by available therapy."

"Adequacy" in this context of unmet medical need is a much broader concept than the mere availability of a treatment option. **We recommend CMS adopt a broader definition of unmet medical need that reflects the diversity of patient preferences and needs.** This was the approach taken in the authorizing statues of the Patient-Centered Outcomes Research Institute which established a more comprehensive approach to evaluating unmet medical needs that included the consideration of "needs, outcomes and preferences" of patients.[2]

For example, a person living with an autoimmune condition might prefer a treatment with fewer side effects or that is easier or more conveniently to administer over one with a slightly higher clinical benefit. To this patient, the quality-of-life improvement from reduced side effects and/or not having to frequently travel to receive a more invasive treatment may weigh heavier in their personal calculation of value than the availability of another treatment. CMS' current definition of unmet medical need in the guidance is not reflective of this heterogeneity of preferences which will have major ramifications for how it will evaluate treatments in the negotiation process.

The implementation of program guidance must be more inclusive of patients, families and caregivers.

CMS has stated intention to include the "patient experience" in the development of program guidance and has signaled a willingness to solicit and consider feedback from a wide range of stakeholders in implementing the Medicare Drug Negotiation Program.

But the short, 30-day timeframes allotted for stakeholders to respond to this and future guidance documents renders this process difficult and severely limits the opportunity for the patient community to meaningfully engage.

We urge the agency to allow for more time for community feedback throughout the implementation of this program moving forward. We believe expanded opportunities for public comment will enhance future program development and could potentially help the agency avoid unintended consequences that could undermine patient access to needed therapies.

Thank you for your consideration and for the opportunity to weigh in on this draft guidance document. Please contact Christian Miller at christian@autoimmune.org should you have any further questions.

Sincerely,

Christian Miller
Policy Manager
christian@autoimmune.org

[2] 42 USC Sec 1320e(d)(1)(A)