August 17, 2026

Mehmet Oz, MD, MBA
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Boulevard Baltimore, MD 21244

RE: Medicare Drug Price Negotiation Program and Medicare Prescription Drug Benefit Program [CMS-4215-P]

Dear Administrator Oz:

The Personalized Medicine Coalition (PMC), a multi-stakeholder group comprising more than 150 institutions from across the health care spectrum, thanks the Centers for Medicare & Medicaid Services (CMS) for the opportunity to submit comments on CMS' proposed rule regarding the Medicare Drug Price Negotiation Program (MDPNP) and Medicare Prescription Drug Benefit Program.[i] The proposed rule represents an important transition in the implementation of the MDPNP by moving many policies that have governed initial price applicability years (IPAYs) 2026 through 2028 from program guidance into regulation, while also establishing several new policies that would apply beginning with IPAY 2029. These include policies addressing fixed-combination drugs that are new formulations, drugs that formerly qualified for the orphan drug exclusion, and consideration of off-label use in determining eligibility and selection for renegotiation. The proposed rule would also codify requirements concerning drug selection, negotiation and renegotiation, stakeholder engagement, evaluation of clinical benefit, and formulary inclusion of selected drugs. We believe many of the policies and requirements in the proposed rule could negatively impact the current and future availability of personalized medicine treatment approaches. PMC's comments build upon those previously shared with CMS on IPAY 2026, IPAY 2027, and IPAY 2028. We further urge CMS to ensure that the negotiation process and renegotiation of previously selected drugs genuinely align with patient needs and preferences, ultimately leading to better health outcomes.[ii]

Personalized medicine is an evolving field in which physicians use diagnostic tests to determine which medical treatments will work best for each patient or use medical interventions to alter molecular mechanisms that impact health. By combining data from diagnostic tests with an individual's medical history, circumstances, and values, health care providers can develop targeted treatment and prevention plans with their patients. Personalized medicine is playing an important role in transforming care and patient outcomes for a range of serious and life-threatening diseases and conditions, helping to shift patient and provider experiences away from trial-and-error medicine and toward a more streamlined process for making clinical decisions.

PMC and CMS share the goal of achieving better health outcomes and lowering costs for patients. We urge CMS to refine its negotiation process so that it does not disrupt the innovation ecosystem and patient access to personalized medicine by ensuring that:

- CMS maintains processes to prevent, monitor, and correct for any unintended, downstream impacts of the MDPNP on patient access to personalized medicine and on pipelines for new personalized medicine treatments and expanded indications;

- CMS recognizes the clinical and societal benefits of personalized medicine and incorporates patients' perspectives on care value;

- CMS' methodology, negotiation process, and renegotiation establish consistency and transparency by communicating how factors considered are weighed and how external data are factored into its decisions;

- CMS refines procedures that allow the exchange of information with manufacturers, patient organizations, and other stakeholders in determining the preliminary price and Maximum Fair Price (MFP) throughout the negotiation process and renegotiation of previously selected drugs; and

- Patients do not face additional barriers accessing negotiated medicines and their treatment alternatives.

Statement of Neutrality

Many of PMC's members will present their own responses to the Medicare Drug Price Negotiation Program and Medicare Prescription Drug Benefit Program Proposed Rule and will actively advocate for those positions. PMC's comments are designed to provide feedback so that the general concept of personalized medicine can advance, and are not intended to impact adversely the ability of individual PMC members, alone or in combination, to pursue separate comments with respect to the proposed rule and/or any rulemaking and guidance that follows.

Considering and Monitoring Impacts of MDPNP on Personalized Medicine

Personalized medicines have accounted for at least a quarter of new drug approvals for each of the past 10 years.[iii] [iv] These medicines are transforming the lives of patients with various stages and types of cancer, rare diseases, chronic conditions, and infectious diseases. PMC previously expressed that the MDPNP could have an outsized effect in discouraging the pharmaceutical industry from bringing additional personalized medicines and expanded indications to the market. Multiple analyses, including those from the Congressional Budget Office (CBO), have called attention to the potential consequences of the Medicare drug price negotiation program, such as canceled research and development and disincentives to invest in small-molecule medicines and therapeutic areas that require incremental innovation.[v] [vi] [vii] **CMS should take every step possible to maintain processes to prevent, monitor, and correct for any unintended, downstream impacts of the MDPNP on pipelines for personalized medicine treatments approaches.**

Orphan drug products and additional rare designations

Only about one quarter of all orphan drugs approved in the last two decades have a single indication.[viii] Continued research and development after an orphan drug's initial approval is crucial and often results in expanded indications within that rare disease or for entirely separate rare diseases for which there is no existing therapy. In fact, a recent analysis found that after the *IRA* was passed, the percentage of drugs with an initial orphan designation that went on to receive a second designation decreased by 48 percent despite a steady

increase observed before the *IRA*.[ix] CMS proposes to clarify how it will identify the date from which to measure the seven- and eleven-year periods for drugs that previously qualified for the orphan drug exclusion. **PMC appreciates CMS' proposal to codify the orphan drug exclusion as amended by the *ORPHAN Cures Act*, which recognizes that development of an additional indication for another rare disease or condition should not, by itself, cause a drug otherwise approved exclusively for rare diseases to lose the exclusion.**

Predictability is especially important where small populations, lengthy evidence-generation timelines, and limited opportunities to recover research and development costs can make decisions about additional indications and continued study particularly sensitive to uncertainty regarding future negotiation eligibility. **PMC encourages CMS to explain clearly the event that triggers loss of the exclusion and the date used to measure time since approval or licensure, including how the CMS will address multiple orphan designations, multiple indications, withdrawn designations or approvals, and changes that occur between selection cycles.**

PMC further encourages CMS to recognize restoration of the exclusion as of the effective date of that withdrawal and to exclude from the applicable seven- or eleven-year period any time during which the drug qualifies for the orphan drug exclusion. This approach would avoid treating a withdrawn indication that is no longer legally approved as though it continued to define the drug's eligibility status and would provide greater predictability for continued rare disease development. **CMS should monitor the impact of this policy on the pursuit or timing of additional indications, evidence generation for very small populations, or continued investment in treatments for rare diseases and serious chronic conditions.**

Other post-approval research and expanded indications

In identifying drug products for negotiation, CMS broadly interprets the *IRA* statute to aggregate drugs for selection based on a single active moiety, or ingredient, across multiple New Drug Applications (NDAs) or Biologics License Applications (BLAs). As drug products age and approach eligibility for price negotiation, companies may be disincentivized to pursue additional indications, which can require additional approvals after the original NDA or BLA approval. PMC is concerned that the negotiation program will deter incremental innovation supported by post-approval research, including the development of expanded indications that provide patients with personalized medicine treatment options.

Research conducted after approval of a new drug is important for advancing personalized medicine. After initial approval of a targeted therapy by FDA, further research provides greater understanding of patients' responses to treatment based on results from molecular diagnostics. This research leads to new or improved treatment indications that contribute to progress in personalized medicine. But smaller patient subpopulations can make it difficult to recoup investment in this research, which can require additional clinical trials and NDAs or BLAs. One white paper examining six products in chronic diseases, rare diseases, and cancer found that over half (seven out of fifteen) of the applications for expanded indications were approved at about the same time or after the product could have been selected to begin negotiation (at seven or eleven years).[x]

Over the past decade, PMC has identified more than 150 expanded indications significant to advancing personalized medicine.[xi] Notably, these expanded indications have had an upward trend in the average time since a drug's initial approval. Since these expanded indications can increase the product's aggregated utilization and risk for earlier selection, the drug price negotiation program can alter manufacturers' decision-making for investing in researching new uses for a drug post approval, potentially affecting patients with serious conditions or unmet needs.

PMC remains concerned about the effects that the aggregation of drugs with the same active moiety or active ingredient in the selection process could have on subsequent research leading to new indications, forms of

administration, and combination products. **We believe CMS should require that, for a drug or biological product to be included in a Qualified Single Source Drug (QSSD), it should be limited to drug products/biological products that are approved/licensed under a single NDA/BLA. In addition, each product within a QSSD should independently meet the age requirement of seven years for a small molecule drug product or eleven years for a biological product.**

CMS proposes a narrow modification to its general fixed-combination drug policy for circumstances in which products offered by the same NDA or BLA holder differ in their active moieties or active ingredients because one product includes an additional active moiety or ingredient that creates a new formulation and enables an alternative route of administration for the shared active moiety or ingredient. Under the proposal, CMS would identify the potential QSSD using all dosage forms and strengths of the shared active moiety or ingredient offered by the same application holder, including both the earlier product and the new fixed-combination formulation. CMS explains that the policy is intended to address program-integrity concerns that could arise if manufacturers shifted utilization toward a new formulation that would otherwise be treated as a separate QSSD and potentially remain outside negotiation for an additional period. **PMC urges CMS not to finalize this proposed modification and instead to continue treating separately approved or licensed fixed-combination products, including products in which an added active ingredient enables a different route of administration, as separate QSSDs**.

A change in route of administration can be clinically and experientially significant even where the principal therapeutic active ingredient remains the same. Depending on the product and condition, a new formulation may reduce infusion time, eliminate the need for venous access, permit administration in a physician office rather than a hospital outpatient department, support administration in the home, decrease travel, reduce time away from employment or caregiving responsibilities, lower the risk of administration related complications, improve tolerability, make treatment feasible for patients with mobility or transportation limitations, reduce caregiver burden, or improve adherence and persistence. A formulation may also make treatment accessible to patients who cannot reasonably receive the original product because of age, disability, comorbidities, prior complications, or the availability of appropriate treatment sites. These differences may not constitute a new therapeutic active ingredient, but they make the products distinct and can meaningfully affect whether and how a patient receives treatment.[xii] [xiii]

Innovations in biologic drugs used to reduce inflammation in autoimmune diseases like arthritis have made injections much less painful, significantly improving the quality of life for patients. Extended-release psychotropic formulations for mental health conditions improve treatment adherence and overall patient outcomes by reducing the frequency of dosing. Combination products, such as fixed-dose combinations for hypertension or HIV, simplify treatment regimens and enhance adherence. Such innovations underscore the importance of encouraging new forms of administration, combination products, and other advancements that enhance patient experience and adherence. **PMC recommends that CMS retain the existing treatment of separately approved or licensed fixed-combination products rather than establishing a negotiation-specific policy that groups them with an earlier product based on a shared active moiety or ingredient.**

Recognizing the Clinical and Societal Value of Personalized Medicine in Determining Clinical Benefit and Therapeutic Alternatives

Drugs with personalized medicine treatment strategies create considerable benefits for patients and society since they are used in a manner that directs them toward patients who are most likely to benefit and away from those who are not. Economic worth of a particular treatment is typically based on analysis of its safety and effectiveness at a population level. In many cases, value assessment methodologies fail to adequately account for the safety and effectiveness benefits that may be realized by individual patients or patient subpopulations.

When assessing value, it is important to consider the holistic benefits of a treatment at the patient, subpopulation, and societal levels.

PMC appreciates CMS' reference to patient experiences in consideration of the clinical benefits of selected drugs and their therapeutic alternatives. Although CMS has broadened its consideration of patient experiences, it is still unclear how input from patients, caregivers, and providers will influence CMS' analysis of clinical benefit and whether CMS may consider the benefit of personalized medicine**. PMC recommends that CMS provide a clear public framework detailing how the agency evaluates qualitative evidence alongside clinical studies, resolves conflicts among evidence sources, considers uncertainty where no evidence exists, and incorporates specific patient subpopulations. Such a framework would help stakeholders understand what information is relevant to CMS and whether particular evidence can materially influence the preliminary price or MFP for a selected drug.**

PMC further urges CMS to consider the following aspects of clinical and societal value related to personalized medicine that advance patient-centered care,[xiv] ensuring that the value of personalized medicine to direct patients toward or away from treatments based on their likelihood to benefit from them is factored into determining the clinical benefits of selected drugs and their therapeutic alternatives:

- **Diagnostic testing strategies:** Diagnostic tests can help guide treatment decisions and determine which treatments will be most effective and safest for any given patient. Such testing is a crucial element of the personalized treatment regimen. For example, the use of companion diagnostics can help define subpopulations of patients who may benefit from a treatment, and those who will not. The availability of diagnostic tests and consideration of test results that help inform treatment decision-making for drugs with biomarker implications must be figured into the value assessment methodology for personalized medicines. PMC encourages CMS to consider the value of applicable diagnostic strategies in its evaluation of unmet medical need and clinical effectiveness.

- **Heterogeneity of treatment effects:** Some patients will experience more or less benefit from a treatment than suggested by the averages reported within clinical trials and population-based data. Health care policies based on averages can misjudge and undervalue personalized medicines simply because the data required for value-based decision-making do not account for patient subpopulations or because long-term efficacy data is not yet available. PMC encourages CMS to consider the full range of patient outcomes and benefits that may not be represented in population average-based data.

- **Patient values and circumstances:** Personalized medicine depends not only on the consideration of a patient's molecular and biological characteristics but also on individual values, clinical and economic circumstances, and the potential impact of a therapy for that patient over the long term. Fundamental patient values and preferences, including the impact of treatment on quality of life, quantity vs. quality of time, functional ability related to illness or treatments, cost of supportive care, and other patient costs of treatment are weighed by patients and their caregivers when deciding on a treatment in consultation with health care providers. Although CMS has attempted to broaden its definition for unmet medical need in past guidance, we believe CMS' definition continues to be too narrow to appropriately assess the value personalized medicines provide to patients with unmet medical needs. PMC encourages CMS to further expand its definition of unmet medical need to formally consider a broad range of patient outcomes and impacts, including unmet medical needs unique to individual patients and patient subpopulations.

- **Treatment efficiency:** Although value assessments generally focus on improvements in effectiveness, they do not generally consider avoiding ineffective or harmful treatment options and reducing the downstream expenses associated with rapid disease progression and/or adverse events. In order to

capture economic as well as clinical value, value assessments need to consider costs and outcomes across health care. As CMS evaluates the costs and benefits of personalized medicines to society, PMC encourages the agency to formally consider a broad range of economic impacts beyond just the proposed consideration of changes to a patient's productivity, including broader cost offsets and societal benefits, like treatment efficiency.

CMS proposes in the rule to draw from multiple sources when identifying therapeutic alternatives, including FDA-approved prescribing information, drug classification systems, major drug compendia, widely accepted clinical practice guidelines, CMS-led literature reviews, peer-reviewed evidence, Medicare claims and other data sets, and information submitted by the primary manufacturer and the public. The proposed framework recognizes that a therapeutic alternative may be in the same or a different pharmacologic class, may include a generic drug or biosimilar, and may involve a specific formulation, dosage form, or strength. CMS further proposes to prioritize clinical appropriateness and may consult with FDA, clinicians, patients, patient organizations, and researchers. We are concerned that the identification of products that may be used for the same condition does not necessarily establish that those products are clinically comparable or reasonably interchangeable for every patient. Therapies used to treat the same disease may differ in indication, line of therapy, mechanism of action, route and site of administration, dosing frequency, contraindications, safety profile, monitoring requirements, interaction with comorbidities, or suitability for particular patient populations. Prior treatment response, disease severity, progression, genetic or biomarker status, and individual patient preferences may also determine whether a product represents a realistic alternative in clinical practice. **PMC encourages CMS to apply the proposed emphasis on clinical appropriateness at the level of the condition, indication, and relevant patient population rather than relying principally on broad pharmacologic or formulary classifications.**

The proposed rule also acknowledges that off-label use can be relevant to both identification of the conditions for which a drug selected for negotiation is used and identification of therapeutic alternatives. Recognition of off-label use is important because such use can represent an established and clinically necessary component of care, particularly in oncology, rare diseases, complex conditions, and areas where evidence or clinical practice develops more quickly than product labeling.

CMS' definition would encompass uses that are not FDA-approved indications but are included in evidence-based clinical practice guidelines and constitute medically accepted indications payable under Medicare Part B, covered under Medicare Part D, or both, taking into account major drug compendia, authoritative medical literature, accepted standards of medical practice, or some combination of those sources. CMS proposes to consider off-label uses when developing the initial offer and to exclude uses intended solely for settings in which the drug is neither payable under Medicare Part B nor covered under Medicare Part D. **The final rule should specify how CMS intends to identify off-label use in practice. Guidelines and compendia will be important sources, but clinically accepted uses may emerge before those sources are updated.**

Providing Clarity and Transparency on Renegotiation of Previously Selected Drugs

The *IRA* anticipated that the clinical and economic value of a drug could evolve over time—due to factors such as new FDA-approved indications, biosimilar entry, or shifts in real-world utilization. Because the statute provides for renegotiation under specified circumstances, CMS will need a structured and transparent process for determining when a selected drug is eligible for and selected for renegotiation. Clinical evidence, indications, therapeutic alternatives, utilization, treatment patterns, and patient experience can change materially after the original negotiation, and the MFP may no longer reflect the information available when a later price applicability year begins.

Relevant developments may include approval of a new indication, emergence of a clinically accepted off-label use, new comparative-effectiveness evidence, changes in safety information, availability of a new therapeutic alternative, changes in the standard of care, identification of a new biomarker-defined population, or new evidence concerning functioning, quality of life, treatment burden, adherence, caregiver experience, or unmet medical need. Changes in use within an existing indication, such as movement to an earlier line of therapy or expansion to a clinically distinct population, may also be meaningful even when the formal indication remains unchanged. **In the final rule CMS should clarify what constitutes a material change in the factors CMS considers for renegotiation and explain how it distinguishes changes that warrant renegotiation from those that can be addressed through continued monitoring.**

Ensuring Patient Access to Negotiated Medicines and Their Treatment Alternatives

The MDPNP could narrow patients' access to existing treatment options. PMC has previously submitted comments to CMS on the difficulties utilization management practices, such as prior authorization and step therapy, can create for patients in accessing the latest treatments and standards of care informed by personalized medicine.[xv] [xvi] [xvii] We are concerned that plans may be incentivized to disadvantage selected drugs with utilization management that is not based on medical appropriateness, potentially exacerbating an already growing trend in the use of step therapy and its embedding in prior authorization requirements.[xviii] [xix] [xx]

Because negotiated drugs are being offered to plans at a lower price, PMC believes negotiated drugs should not face additional cost-control practices that could limit eligible Medicare beneficiaries' access to them. PMC supports CMS' requirement that Medicare Part D plan formularies include each selected Part D drug for which an MFP is in effect, however, a selected drug may remain technically included while being placed on a less favorable tier, subjected to prior authorization or step therapy, restricted to a narrow pharmacy network, or made more difficult to access than another product used for the same condition. These policies can affect whether the MFP produces a meaningful affordability benefit for the beneficiary. They can also result in treatment switching, delayed initiation, interruption of stable therapy, or abandonment of treatment. **PMC urges CMS to clarify in the final rule that selection of a drug or establishment of an MFP does not constitute a clinical rationale for more restrictive utilization management. PMC also encourages CMS to address how it plans to monitor and rectify the real-world impacts of any utilization management, while ensuring that patient access to negotiated drugs and competitors within their class are not hampered.**

Facilitating Meaningful Stakeholder Engagement

To help build public trust in the negotiation process and ensure predictability informs stakeholder participation, CMS must be transparent about how it considers information provided. The current process is insufficient to ensure that stakeholder contributions have influenced policy outcomes or to learn why their feedback was ultimately not acted upon. The transition from annual guidance to regulation can provide greater predictability for patients, patient organizations, manufacturers, plans, providers, and other stakeholders, and it can make the program's policies easier to understand and evaluate across negotiation cycles. This codification can also reduce the risk that policies change without sufficient notice or opportunity for public input. However, several policies proposed for codification involve methods that have not yet been fully tested or whose effects cannot yet be comprehensively evaluated.

The first MFPs took effect this year, MFP effectuation for Medicare Part B drugs still in development, and the relationship among negotiated prices, formulary design, provider participation, product availability, treatment switching, and beneficiary out-of-pocket costs is not yet clear. **CMS should treat the final rule as a foundation rather than the conclusion of policy development. Periodic public evaluation of the MDPNP, publication of implementation findings, identification of policies that may require revision, and**

meaningful opportunities for other stakeholders to comment on future changes would support program improvement.

Conclusion

PMC and CMS share the goal of achieving better health outcomes and lowering costs for patients. As the agency continues to implement the drug price negotiation program, we urge CMS to carefully consider these comments and ensure it maintains innovation in personalized medicine. If you have any questions about the contents of this letter, please contact me at 202-499-0986 or cbens@personalizedmedicinecoalition.org.

Sincerely,

Cynthia A. Bens
Senior Vice President, Public Policy

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[i] Centers for Medicare & Medicaid Services. Medicare Program: Medicare Drug Price Negotiation Program and Medicare Prescription Drug Benefit Program. June 16, 2026. https://www.regulations.gov/document/CMS-2026-2080-0001 (accessed August 11, 2026).
[ii] Personalized Medicine Coalition. Comment letter on Medicare Drug Price Negotiation Program: Initial Memorandum, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2026, and Solicitation of Comments. April 18, 2023. https://www.personalizedmedicinecoalition.org/Userfiles/PMC-Corporate/file/comment-letter1.pdf (accessed August 11, 2026).
[iii] O'Brien, John. "Branded Drug Report 2023: John O'Brien, NPC." *Chain Drug Review*. January 9, 2023. https://www.chaindrugreview.com/branded-drug-report-2023-john-obrien-npc/ (accessed August 11, 2026).
[iv] Personalized Medicine Coalition. Personalized Medicine at FDA: The Scope & Significance of Progress in 2023. February 29, 2024. https://www.personalizedmedicinecoalition.org/wp-content/uploads/2024/02/report-3.pdf (accessed August 11, 2026).
[v] Congressional Budget Office. *CBO's Simulation Model of New Drug Development: Working Paper 2021-09*. August 26, 2021. https://www.cbo.gov/publication/57010 (accessed August 11, 2026).
[vi] Vital Transformation. Total Market Impact of Price Controls in Medicare Parts D and B. July 28, 2022. https://vitaltransformation.com/2026/05/preprint-new-research-the-inflation-reduction-acts-impact-upon-late-stage-rd/ (accessed August 11, 2026).
[vii] Avalere. *Drug Pricing Bill Could Reduce Manufacturer Revenue by Over $450B*. July 22, 2022. https://avalere.com/insights/drug-pricing-bill-could-reduce-manufacturer-revenue (accessed August 11, 2026).
[viii] Chambers, James D. "Follow-On Indications for Orphan Drugs Related to the Inflation Reduction Act." *JAMA Network Open*. August 15, 2023. https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2808362 (August 11, 2026).
[ix] National Pharmaceutical Council. *Policy & Evidence Brief: Early Signals of the IRA on Orphan Drugs*. May 15, 2025. https://www.npcnow.org/resources/early-signals-ira-orphan-drugs (accessed August 11, 2026).
[x] Avalere. *An Assessment of Regulatory Interpretation of Qualifying Single- Source Drugs in Medicare Negotiation*. April 22, 2024. https://avalere.com/wp-content/uploads/2024/04/An-Assessment-of-Regulatory-Interpretation-of-Qualifying-Single-Source-Drugs-in-Medicare-Negotiation.pdf (accessed August 11, 2026).
[xi] Personalized Medicine Coalition. *Personalized Medicine at FDA: The Scope & Significance of Progress in 2024.* April 2025. https://www.personalizedmedicinecoalition.org/wp-content/uploads/2025/06/PMC_PM_at_FDA_The_Scope__Significance_of_Progress_2024_1.pdf (accessed August 11, 2026).
[xii] Stewart, K., et al., "Preference for Pharmaceutical Formulation and Treatment Process Attributes." Patient Preference and Adherence. July 27, 2016. https://www.dovepress.com/preference-for-pharmaceutical-formulation-and-treatment-process-attrib-peer-reviewed-fulltext-article-PPA (accessed August 11, 2026).
[xiii] Overton, P.M., et al., "Patient Preferences for Subcutaneous versus Intravenous Administration of Treatment for Chronic Immune System Disorders: A Systematic Review." Patient Preference and Adherence. April 19, 2021. https://www.dovepress.com/patient-preferences-for-subcutaneous-versus-intravenous-administration-peer-reviewed-fulltext-article-PPA (accessed August 11, 2026).
[xiv] Personalized Medicine Coalition. *Personalized Medicine and Value Assessment Frameworks: Context, Considerations, and Next Steps*. December 14, 2017. https://www.personalizedmedicinecoalition.org/Userfiles/PMC-Corporate/file/PM_and_VAFs.pdf (accessed August 11, 2026).

[xv] Personalized Medicine Coalition. *Comment letter on Medicare Program; Contract Year 2025 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, etc. (CMS–4205–P)*. January 5, 2024. https://www.personalizedmedicinecoalition.org/Userfiles/PMC-Corporate/file/PMC-Comment-Letter-on-Medicare-Advantage-RFI.pdf (accessed August 11, 2026).
[xvi] Personalized Medicine Coalition. *Comment letter on Medicare Program; Request for Information on Medicare (CMS-4203-NC)*. August 31, 2022. https://www.personalizedmedicinecoalition.org/Userfiles/PMC-Corporate/file/PMC-Comment-Letter-on-Medicare-Advantage-RFI.pdf (accessed August 11, 2026).
[xvii] Personalized Medicine Coalition. *Comment Letter on Step Therapy for Part B Drugs in Medicare Advantage (MA)*. October 15, 2018. https://www.personalizedmedicinecoalition.org/Userfiles/PMC-Corporate/file/PMC_Comment_Letter_Step_Therapy.pdf (accessed August 11, 2026).
[xviii] Snow, Jennifer et al. The Impact of Step-Therapy Policies on Patients. Xcenda. https://www.asdhealthcare.com/insights/moving-medicare-coverage (accessed August 11, 2026).
[xix] American Cancer Society Cancer Action Network (ACS CAN). Utilization Management in Breast Cancer and Hepatocellular Carcinoma. May 21, 2024. https://www.fightcancer.org/sites/default/files/acs_can_ma-pd_plan_um_analysis_white_paper_final.pdf (accessed August 11, 2026).
[xx] American Cancer Society Cancer Action Network (ACS CAN). Step Therapy in Medicare Part D Oncology Drugs. May 21, 2024. https://www.fightcancer.org/sites/default/files/acs_can_part_d_formulary_analysis_final.pdf (accessed August 11, 2026).