June 15, 2026

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

RE: Medicare and Medicaid Programs; Patient Protection and Affordable Care Act; Interoperability Standards and Prior Authorization for Drugs for Medicare Advantage Organizations, Medicaid Managed Care Plans, State Medicaid Agencies, Children's Health Insurance Program (CHIP) Agencies and CHIP Managed Care Entities, and Issuers of Qualified Health Plans on the Federally-Facilitated Exchanges [CMS-0062-P]

Submitted electronically via regulations.gov

Dear Dr. Oz:

The undersigned national organizations, representing digestive disease patients and physicians appreciate the opportunity to respond to several elements of the Centers for Medicare &

Medicaid Services (CMS) proposed rule, as published in the *Federal Register* on April 14, 2026, to improve the electronic exchange of health care data and streamline processes related to prior authorization (PA) by increasing the interoperability of systems used across the health care industry.

The use of PA is resulting in denials and delays for medically necessary care and treatments, and the administrative burden associated with PA on gastroenterologists and other physicians, as well as the impact of PA on clinical recommendations, are well documented.[1,2,3] We acknowledge the steps that have been taken by CMS to help relieve the burden of PA on clinicians and to make the PA process more transparent. The truth is, however, that the PA data required to be made public by health plans are often difficult to find on health plan websites, reported in inconsistent formats, and aggregated at a level too high to show what is happening to specific services, such as diagnostic endoscopy or advanced therapeutic procedures. High approval rates on paper may also mask delays that effectively function as denials for patients with time-sensitive conditions. Greater transparency is required and is why our societies strongly advocate for the reporting by health plans of PA metrics at a granular level, including approvals and denials by service and item category, as well as the number of requests denied and appealed using AI or similar technology.

In gastroenterology, PA denials and delays in decision making have become particularly problematic in the prescribing of biologics and other pharmacologic therapies to patients, both children and adults, including, but not limited to, inflammatory bowel disease (IBD), eosinophilic esophagitis (EoE), and liver diseases and disorders. We commend CMS for acknowledging through this proposed rule that many of the existing interoperability requirements for the PA of non-drug items and services should be extended to drugs to further reduce patient and provider burden. We also appreciate CMS' interest in understanding how technology could be used to streamline the step therapy process used by insurers and their pharmacy benefit managers (PBMs). As such, we offer comment on the following aspects of the proposed rule:

- Electronic PA for All Drugs that Require PA
- Transparency of PA Use by Impacted Payers
- Step Therapy for Drugs and Biologics
- Waiver of Step Therapy for 'Underwater' Biologics

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[1] Shah ED, Amann ST, Hobley J, Islam S, Taunk R, Wilson L. 2021 National Survey on Prior Authorization Burden and Its Impact on Gastroenterology Practice. Am J Gastroenterol. 2022 May 1;117(5):802-805. doi: 10.14309/ajg.0000000000001728. Epub 2022 Mar 17. PMID: 35296630; PMCID: PMC9060934.

[2] Kahn SA, Bousvaros A. Denials, Dilly-dallying, and Despair: Navigating the Insurance Labyrinth to Obtain Medically Necessary Medications for Pediatric Inflammatory Bowel Disease Patients. J Pediatr Gastroenterol Nutr. 2022 Oct 1;75(4):418-422. doi: 10.1097/MPG.0000000000003564. Epub 2022 Jul 15. PMID: 35836325.

[3] American Medical Association. 2025 AMA Prior Authroization Survey. https://www.ama-assn.org/press-center/ama-press-releases/ama-survey-prior-authorization-reform-pledge-falls-short-physicians

ELECTRONIC PA FOR ALL DRUGS THAT REQUIRE PA

Our societies strongly support CMS' proposal to expand the 2024 interoperability and PA framework to include drugs, both those covered under a medical benefit and those covered under a pharmacy benefit, using a combination of standards, including the HL7® FHIR® standards that compose the PA Application Programming Interface (API) and the National Council for Prescription Drug Programs (NCPDP) standards required for covered Part D drugs.

PA requirements for medical- and pharmacy-benefit drugs are also among the most administratively burdensome utilization management practices faced by gastroenterology (GI) practices. Current processes remain highly fragmented and frequently rely on manual fax, telephone, or portal-based workflows that impede timely patient care.

However, **CMS could strengthen the proposal by:**

- Clarifying that all utilization management aspects related to drugs covered under a medical or pharmacy benefit, including site-of-care and dose escalation requests, be supported through the PA API and be included in transparency requirements.

- Explicitly prohibiting payers from requiring clinicians to submit duplicative documentation through proprietary portals when equivalent information has already been transmitted through the standardized API.

It is also critically important that there be some level of interoperability between medical and pharmacy benefit standards when establishing electronic PA for drugs. It is common in IBD for therapies to cross the medical and pharmacy benefit categories. For example, a biologic may begin as IV induction under the medical benefit and later transition to subcutaneous maintenance under the pharmacy benefit. If pharmacy and medical benefit data are not interoperable, the payer may incorrectly view the patient as "new" to therapy or lacking documentation, even though the therapy is a continuation of established care. In addition, clinicians have all experienced situations in which IV induction is approved, only to have the subcutaneous maintenance denied.

Response Timeframes

Like non-drug medical items and services, impacted payers must be required to respond to PA requests for drugs in a timely manner. Delays associated with PA and step therapy are not merely administrative inconveniences but can result in clinically significant patient harm. Published literature shows that delays resulting from health plan utilization management tactics are often associated with increased disease activity, emergency department visits, hospitalizations and otherwise avoidable health care utilization. For patients with GI inflammatory conditions, delayed initiation of treatment or interruption in treatment can result in loss of response to

treatment, immunogenicity, worsening disease and increased risk of surgery.[4] We support CMS' proposals to:

- Require Qualified Health Plans (QHP) issuers on the Federally Facilitated Exchanges (FFEs) to make PA decisions no later than 72 hours for standard requests and 24 hours for expedited requests for all drugs.

- Require state Medicaid FFS programs, Medicaid managed care plans, and Children's Health Insurance Program (CHIP) managed care entities to make PA decisions for drugs within a timeframe that aligns with applicable existing decision timeframe requirements.

- Require state CHIP Fee for Service (FFS) programs to make prior authorization decisions no later than 24 hours for prescription drugs for which Federal Financial Participation (FFP) is available.

While our organizations support CMS' proposed timelines, we encourage the Agency to adopt the shortest feasible timelines across all payer categories. We recommend that all prior authorization requests involving liver transplant patients, including both transplant candidates and transplant recipients, be subject to expedited review within 24 hours regardless of stated acuity. Transplant patients frequently require urgent access to immunosuppressive therapies, anti-infectives, and other specialty medications where delays can result in graft dysfunction, organ rejection, hospitalization, or other serious complications. Similarly, transplant candidates often require rapid treatment adjustments to preserve stability and maintain transplant eligibility. Given the uniquely time-sensitive nature of transplant care, a uniform expedited standard for transplant-related prior authorizations is warranted.

Patients with active GI disease often require urgent access to therapy to prevent irreversible complications. Delays in authorization can result in hospitalization, surgery, bowel damage, corticosteroid dependence, malnutrition, or disease progression.

We further recommend that CMS:

- Finalize the proposed expedited review timelines and strengthen enforcement mechanisms for noncompliance.
- Require automatic approval when payers fail to meet applicable review deadlines.
- Require continuity-of-care protections that maintain access to existing therapy during pending appeals or patient transitions between health plans.

Reason for Denial in Prior Authorization Responses

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[4] Constant BD, Long MD, Scott FI, Higgins PDR. Insurer-Mandated Medication Utilization Barriers are Associated With Decreased Insurance Satisfaction and Adverse Clinical Outcomes: An Inflammatory Bowel Disease Partners Survey. *Am J Gastroenterol*. 2024;119(10):2070-2078. doi:10.14309/ajg.0000000000002931 [PubMed] [1]

Our organizations strongly support that state Medicaid and CHIP FFS programs, Medicaid managed care plans, CHIP managed care entities, and QHP issuers on the FFEs be required to provide a specific reason to providers when denying a prior authorization request for drugs, as is already required by Medicare Advantage (MA) plans. **This requirement should apply regardless of the method used to send the PA request or decision.** Whether a drug is denied because of a payer's formulary, a utilization management policy, labeling indications, or site-of-service restrictions, the prescribing clinicians must know the reason so they can advocate most effectively on behalf of their patients.

Generic denial language is insufficient and contributes substantially to administrative burden, repeated submissions, delayed treatment, and patient confusion. Clinicians frequently receive vague denial notices stating only that a request "does not meet medical necessity criteria" without identifying the specific guideline, documentation deficiency, step-therapy requirement, or clinical rationale underlying the denial. Such practices also impede efficient appeals.

CMS should require that drug denial notices include:

- Specific clinical criterion or policy provision not satisfied.
- Identification of missing documentation.
- Citation to the precise payer policy or guideline relied upon in making the determination.
- Identification of any required step therapy protocols.
- Information regarding the clinical qualifications of the reviewer issuing the denial.
- Clear instructions for appeal and peer-to-peer review.

Further, **CMS should also require that adverse determinations be reviewed by appropriately qualified specialists with relevant expertise in the disease or condition for which the treatment is being requested.**

PA Use Transparency by Impacted Payers

Under the 2024 CMS Interoperability and Prior Authorization final rule, impacted payers must report on their websites certain PA metrics for non-drug items and services by percentage, including the percentage of PAs that were approved, denied, approved after appeal, and approved after the timeframe for review was extended. **We strongly support CMS' proposal to require impacted payers to report for non-drug items and services a numeric count for each of those metrics, in addition to the percentages. We support the same requirements for drugs, although plan-specific, drug-level reporting would be preferable.** Numeric reporting will also allow regulators, clinicians and researchers to better evaluate payer practices and identify outlier behavior. Further, we recommend that reporting be standardized across health plans.

We support the addition of the following metrics that are complementary to existing metrics for non-drug items and services. **All PA metrics that must be reported by impacted payers for medical items and services should be extended to drugs.**

- Total number and percentage of standard PA requests for non-drug items and services that remain denied after appeal during the reporting period.

- Total number and percentage of expedited PA requests for non-drug items and services that remain denied after appeal during the reporting period.

- Total number and percentage of standard PA requests for non-drug items and services for which the timeframe for review was extended, and the request was denied during the reporting period.

- Total number and percentage of expedited PA requests for non-drug items and services for which the timeframe for review was extended, and the request was denied during the reporting period.

- Total number and percentage of expedited PA requests for non-drug items and services for which the timeframe for review was extended, and the request was approved during the reporting period.

- Total number and percentage of expedited PA requests for non-drug items and services that were approved after appeal during the reporting period.

For appeals, we support CMS' proposal to include appeals reviewed internally by the impacted payer, as well as by external organizations an impacted payer may contract with to review and process appeals. We also support applying all existing and newly proposed reporting metrics to PA reporting for drugs.

Reporting of PA metrics by impacted payers would be significantly strengthened by the reporting of all metrics by item and service and stratified by geographic region. This level of granularity will allow for more useful and complete information.

For drugs, transparency would be greatly enhanced by requiring impacted payers to publicly report the following PA metrics:

- Delineation of all required data by medical and pharmacy benefit.
- Delineation by therapeutic category, drug class and indication.
- Rates of repeated PA for patients stable on current/maintenance therapy.
- Average response times for standard and expedited requests broken down by medical items and services, and drugs (broken down by medical and pharmacy benefits).

STEP THERAPY FOR DRUGS AND BIOLOGICS

We appreciate that CMS is soliciting public comment on whether increased interoperability of information technology (IT) systems across payers could be used to make step therapy and other utilization management practices more transparent. This is a worthy endeavor, however, patients with GI illnesses need relief now from step-therapy practices. **Our organizations implore CMS to establish rigorous federal safeguards to protect vulnerable patients from the harmful consequences of step therapy, or "fail first," insurance mandates.** Our experience with the suffering of tens of thousands of patients over many years makes clear that technological improvements alone will be insufficient to reform the practice of step therapy to the extent needed to ensure patients avoid negative consequences.

Diseases of the gastroenterological tract are complex, chronic, and often progressive conditions that – when improperly treated — can cause death and disability. Effectively managing these diseases often requires pharmacologic or biologic treatment that is driven by a highly personalized long-term strategy overseen by a gastroenterologist. When insurers impose step therapy, they override doctor-prescribed treatment plans, forcing patients to cycle through alternative medications regardless of their clinical need. Absent regulatory oversight, there is little incentive for PBMs to preemptively exclude a patient from step therapy when they profit from steering patients to ineffective medications.

Step Therapy Leads to Negative Outcomes

Far too often, patients are forced to try multiple insurance-preferred medications (multiple 'steps') before obtaining access to the medication that their health care provider originally prescribed based on the specifics of their disease status and medical history. For patients with digestive diseases, these mandatory delays often carry severe health consequences.

In IBD, for example, step therapy commonly creates barriers when payers require failure of corticosteroids, thiopurines, methotrexate, or a payer-preferred biologic before approving the therapy selected by the treating gastroenterologist. This is especially problematic in children because treatment selection often depends on severity, growth failure, pubertal delay, extra-intestinal manifestations, prior infection risk, family logistics, route of administration, therapeutic drug monitoring, and the need for rapid steroid-sparing disease control. Common examples of step therapy include:

- A child with moderate-to-severe Crohn's disease, growth failure, and elevated inflammatory markers is prescribed an anti-TNF therapy or other advanced therapy, but the payer requires failure of steroids or immunomodulators first. This is the most common scenario that pediatric patients and clinicians encounter.

- A patient stable on infliximab after prior loss of response or intolerance to other therapies changes insurance and is required to repeat step therapy despite being in remission.

- A patient stable on vedolizumab, ustekinumab, risankizumab, adalimumab, or another advanced therapy changes insurance and must re-document failure of older therapies before continuation is approved.

The dangers of unmitigated step therapy protocols include:

- **Irreversible Disease Progression:** Step therapy delays access to targeted advanced therapies (such as biologics) that are superior in halting disease progression. Active, unmitigated digestive disease significantly increases the risk of malnutrition, dehydration, developmental delays, strictures, fistulas, bowel perforations, and their resulting need for major surgery, and/or hospitalization

- **Direct Contradiction of Clinical Guidelines:** Fail-first protocols directly conflict with the Clinical Practice Guidelines for digestive disorders which recommend the early use of high-efficacy advanced therapies over step-up approaches to improve long-term outcomes and halt disease progression.[5,6]

- **Compounded System Costs:** Step therapy fails as a cost-cutting tool. Forcing patients to use less safe or ineffective drugs can lead to preventable emergency room visits, prolonged hospitalizations, expensive surgeries, and other health complications.[7] Multiple studies have shown that the delays caused by step therapy ultimately lead to increased health system costs[8,9] even within the same plan year.[10,11,12] In a recent national survey of IBD patients, 85 percent who were subjected to step therapy reported they experienced negative health outcomes when they were unable to or delayed in obtaining

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[5] https://gastro.org/news/new-aga-guideline-streamlines-crohns-disease-treatment/

[6] Anderson KL, Anand R, Feuerstein JD. Insurance companies' poor adherence to guidelines for moderate-to-severe ulcerative colitis/Crohn's disease management. Am J Gastroenterol. 2024;119(7):1417-1420. doi:10.14309/ajg.0000000000002720

[7] Joy S, Mire RD. Mitigating the negative impact of step therapy policies and nonmedical switching of prescription drugs on patient safety: A position paper of the American College of Physicians. American College of Physicians. Updated 2020. Accessed May 4, 2026. https://www.acponline.org/sites/default/files/acp-policy-library/policies/step_therapy_nonmedical_switching_prescription_drugs_policy_2020.pdf.

[8] Mark TL, Gibson TB, McGuigan KA. The effects of antihypertensive step-therapy protocols on pharmaceutical and medical utilization and expenditures. Am J Manag Care. 2009 Feb;15(2):123-31. PMID: 19284809.

[9] Howell S, Yin PT, Robinson JC. Quantifying the economic burden of drug utilization management on payers, manufacturers, physicians, and patients. Health Aff (Millwood). 2021;40(8):1206-1214. doi:10.1377/hlthaff.2021.00036

[10] Farley JF, Cline RR, Schommer JC, et al. Retrospective assessment of Medicaid step-therapy prior authorization policy for atypical antipsychotic medications. Clin Ther. 2008;30(8):1524-1539. DOI: 10.1016/j.clinthera.2008.08.009

[11] Panzer PE, Regan TS, Chiao E, Sarnes ME. Implications of an SSRI generic step therapy pharmacy benefit design: An economic model in anxiety disorders. Am J Manag Care. 2005;11(12 Suppl):S370-S3709. PMID: 16236019

[12] Murawski MM, Abdelgawad T. Exploration of the impact of preferred drug lists on hospital and physician visits and the costs to Medicaid. Am J Manag Care. 2005;11:SP35-42. PMID: 15700908

access to their prescribed medications.[13,14] These complications are in addition to the incalculable human cost of avoidable pain, suffering, and loss of function.

- **Physician Administrative Burden:** Appealing step therapy protocols imposes an unsustainable administrative burden on clinicians, redirecting limited clinical staff away from direct patient care to manage insurer paperwork.[15]

Recommended Federal Protections and Guardrails

To avoid the dire consequences of unregulated step-therapy protocols, plans should institute a standard process that patients and providers can use to request exceptions from step therapy. Plans should be required to respond to exception requests within 72 hours of receipt under normal circumstances, and within 24 hours in the case of a medical emergency.

We recommend that patients who meet the following criteria should be exempted from step therapy altogether:

- The patient already tried and failed on the insurance-preferred drug(s).
- Delayed treatment will cause irreversible health consequences.
- The insurance-required drug(s) will cause harm to the patient.
- The insurance-required drug(s) will prevent a patient from working or fulfilling activities of daily living.
- The patient is stable on their current medication.

When a request for a step-therapy exception is denied, payers should be required to include patient-specific information detailing the payer's clinical rationale for denying the request (e.g., national medical society's guidelines, peer-reviewed clinical literature), the alternative treatment covered by the plan, and a description of the right to an appeal.

We are concerned that many of the insurance programs under CMS' jurisdiction (e.g., Medicaid, CHIP, and the *Affordable Care Act* (ACA) exchanges) do not regularly offer the standard exception process contained in 42 CFR § 423.578 This is the case even though the populations covered by Medicaid and CHIP are among the most vulnerable in the nation and are particularly susceptible to negative health consequences caused by delayed access to medically necessary care. In addition, plans sold on the state ACA exchanges often do not offer an exception process at all, and where they do, the process varies widely. This creates a confusing patchwork of

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[13] Jordan AA, Bhat S, Ali T, Brunskill SR, Clusen NA, Maltz RM, Moise C, Sun X, Thomas HJ, Ray C, Harkins-Schwarz M, Ehrlich OG. Healthcare Access for Patients With Inflammatory Bowel Disease in the United States: A Survey by the Crohn's & Colitis Foundation. Inflamm Bowel Dis. 2025 Jul 7;31(7):1819-1832. doi: 10.1093/ibd/izae237. PMID: 39377748; PMCID: PMC12235136.

[14] Zisman E, Alizadeh M, Rossmann L. Insurance Denial of Biologic Therapy is Associated With Reduced Remission Rates in Inflammatory Bowel Disease Patients. Gastro Hep Advances, 2025; 4

[15] https://gastro.org/advocacy-and-policy/policies-affecting-gi/regulatory-relief-for-gastroenterologists/

exceptions and appeals processes across the nation. **We urge you to improve patient care and payment system efficiency by standardizing a meaningful step-therapy exemption and exception process across all programs administered by your office.**

We also urge the Administration to take regulatory steps to protect patients from being forced to move to a new therapy when they are stable on existing therapy. This practice, referred to as 'non-medical switching,' is fueled by drug rebating arrangements in exchange for preferred formulary status and should be strictly prohibited without the explicit approval of the treating clinician. The practice of non-medical switching has pervaded the treatment of IBD, requiring patients that have already achieved remission on current therapy to switch to a different product, creating risk of interruption, immunogenicity, flare, or loss of response.

Standardize and Streamline the Step Therapy Exceptions Process

Currently, there is no standardized approach to applying step-therapy criteria, and payers' methods for obtaining documentation to support a patient's step therapy history vary widely.

Typically, under current payer practices, when requesting a waiver or exception to step therapy, GI teams typically must submit a letter of medical necessity plus extensive supporting documentation and references. This may include diagnosis, disease phenotype, disease severity, prior medication history, dates and duration of prior therapies, reason for failure or discontinuation, steroid exposure, hospitalization history, lab results, endoscopy reports, imaging, growth data, therapeutic drug monitoring, adverse reactions, and prior payer approvals.

If a patient changes insurance, this process often starts over. Even if the patient is stable on current therapy, the new payer may not accept the PA decision, prior step-therapy fulfillment, or clinical rationale from the previous payer. The burden then falls on the provider team and family to reconstruct records, obtain external documentation, and resubmit information through a new portal, fax process, or peer-to-peer review.

In the end, clinicians bear the brunt of this documentation submission. The American Medical Association estimates that physician practices spend, on average, 12 hours per week managing the administrative burden associated with insurer-mandated step therapy and prior authorization.

To ensure the technology solution is designed with both patients and providers in mind, **we recommend that CMS develop a technology platform to standardize the electronic submission of step-therapy information and the exception process across all payers, including standard forms and instructions for step-therapy exceptions.**

Payer-to-payer and provider-payer data exchange should include enough information to determine whether a patient has already satisfied step therapy or has a clinically justified exception. **At minimum, this should include:**

- Current medication, dose, route, duration and target therapeutic level.
- Prior therapies tried, with dates and outcomes.
- Documented intolerance, contraindication, non-response, loss of response, or adverse reaction.
- Prior step-therapy exceptions or approvals.
- Objective disease activity data, when available.
- Treating specialist attestation that the patient is stable and interruption would create clinical risk.

A major pediatric GI issue is that therapies often cross categories. For example, a biologic may begin as IV induction under the medical benefit and later transition to subcutaneous maintenance under the pharmacy benefit. Similarly, site-of-care mandates may shift an infusion drug between hospital outpatient, home infusion, specialty pharmacy, and external infusion center workflows. **If pharmacy and medical benefit data are not interoperable, the payer may incorrectly view the patient as "new" to therapy or lacking documentation, even though the therapy is a continuation of established care**. In addition, we have all seen cases where IV induction is approved and given, only to have the subcutaneous maintenance denied. **We strongly recommend that step-therapy determinations be transferable across payers and across benefit categories.** The clinical question should not reset because of the insurance plan, benefit type, site of care, or route of administration changes.

We also recommend that CMS require payers to provide the following information in plain language, using a consistent format, to patients and providers:

- Patient-specific utilization management requirements, including which treatments, services, and prescription drugs have step-therapy requirements, PA requirements, and/or formulary restrictions.
- Patient-specific cost-sharing information for each treatment, service, and prescription drug.
- For prescription drugs and services subjected to step therapy, a clear description of the exact step-therapy requirement(s) for each applicable service/drug.
- Each step-therapy protocol must be based on documented, conclusive clinical evidence that the insurance-required medication/treatment is as effective and safe as the initial, provider-prescribed medication.
- Clear description of the criteria used to determine the appropriateness of a step-therapy exception.
- Effective dates of step therapy policies.

It is important to continually evaluate the effectiveness of new policies, systems, and procedures. Therefore, **we also recommend CMS build future technology systems with public reporting in mind. We believe that, at a minimum, there should be publicly available data (as allowed under existing patient privacy protections) on the following step-therapy variables:**

- Total number of step-therapy exception requests.
- Medications, diagnostic tests, and/or procedures that are subject to step therapy.
- The health indication that the medication/test/procedure is used to treat.
- The results of all step-therapy exception requests (approvals, denials).
- Reasons for denials.
- Total number of denials overturned on appeal.

Patients Need Continuity of Care Across *and* Within Plans

Supporters of step therapy often argue that it prevents medically unnecessary care or direction to higher-cost medications when cheaper options suffice.[16] On the surface, this argument would hold up most strongly in newly diagnosed patients with no prior treatment history because, in theory, a less expensive, straightforward intervention may be sufficient to manage their disease. However, research has repeatedly demonstrated that even in these circumstances, step therapy often leads to downstream harm (e.g., increased risk of hospitalization) and increased costs that could have been prevented by earlier initiation of the originally prescribed medication. [17,18,19]

But, the basis for step therapy's alleged cost savings and prevention of unnecessary care proves categorically untrue for patients who have found stability on a medication after insurer-preferred medications have failed. Whether the patient's plan prefers a medication that provides clinical stability does not alter the medical reality of patients who have already failed to achieve this stability with the options favored by their insurer. In this all-too-frequent instance, there is no reasonable clinical evidence to suggest that repeatedly trying the payor-preferred medication will ultimately prove successful. Instead, the preponderance of evidence shows that patients who are forced to halt an effective treatment experience significant declines in health, leading to higher health care utilization (and associated higher costs) and poorer health outcomes.[20]

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[16] Sachs RE, Kyle MA. Step therapy's balancing act – Protecting patients while addressing high drug costs. N Engl J Med. 2022;386(10):901-904. DOI: 10.1056/NEJMp2117582.

[17] Mark TL, Gibson TB, McGuigan KA. The effects of antihypertensive step-therapy protocols on pharmaceutical and medical utilization and expenditure. Am J Manag Care. 2009;15(2):123-131. PMID: 19284809.

[18] The Moran Company. Cost-motivated treatment changes in Medicare Part B: Implications for non-medical switching. Institute for Patient Access. September 2016. Accessed May 4, 2026 from: https://instituteforpatientaccess.org/wp-content/uploads/2018/07/Switching-Study-Report-FINAL.pdf

[19] Florenzo B, Lyons CE, Smith AD, Remington C, Flower RH, Bryer B. Mandated step therapy for dupilumab delays the inevitable. J Dermatolog Treat. 2024;35(1):2328185. DOI: 10.1080/09546634.2024.2328185.

[20] Joy S, Mire RD. Mitigating the negative impact of step therapy policies and nonmedical switching of prescription drugs on patient safety: A position paper of the American College of Physicians. American College of Physicians. Updated 2020. Accessed May 4, 2026. https://www.acponline.org/sites/default/files/acp-policy-library/policies/step_therapy_nonmedical_switching_prescription_drugs_policy_2020.pdf.

In addition, removing a patient from a biologic medication overlooks the fact that many of these advanced therapies are highly immunogenic.[21,22] Insurance-mandated interruptions to ongoing therapy run the documented risk of the patient developing anti-drug antibodies, which hinder their body's future response to the medication. In these cases, the medication that once worked for a patient will no longer provide relief once the therapy is stopped, which only leads to unnecessary suffering for the patient and additional costs to the system.[23,24] This is particularly dangerous in disease states with few available treatment options. For this reason, many of our patients must maintain continued access to the biologics that have stabilized their diseases.[25,26,27]

There are numerous examples of payers requiring patients to repeat the arduous, mentally and physically taxing, and medically harmful process of step therapy.[28,29] This occurs both when a patient switches their insurance *and* when their existing plan changes its formulary. Patients who are not changing jobs or switching carriers often face step therapy at the beginning of each plan year or when their insurance updates its utilization management requirements. As detailed above, requiring patients to repeat step therapy leads to significant downstream harm, increased health care utilization, and ultimately increases costs.

The following is an example from 2026 that underscores the importance of regulatory measures to rein in the abusive step therapy practices.

A 7-year-old patient with chronic functional constipation who failed multiple over-the-counter laxatives. The patient was prescribed Linzess (linaclotide) in 2024 — a Food and Drug Administration (FDA)-approved medication for this exact condition and age group. With this

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[21] Thomas SS, Borazan N, Barroso N, Duan L, Taroumian S, Kretzmann B, Bardales R, Elashoff D, Vangala S, Furst DE. Comparative Immunogenicity of TNF Inhibitors: Impact on Clinical Efficacy and Tolerability in the Management of Autoimmune Diseases. A Systematic Review and Meta-Analysis. BioDrugs. 2015 Aug;29(4):241-58. doi: 10.1007/s40259-015-0134-5. PMID: 26280210.

[22] Vaisman-Mentesh A, Gutierrez-Gonzalez M, DeKosky BJ, Wine Y. The Molecular Mechanisms That Underlie the Immune Biology of Anti-drug Antibody Formation Following Treatment With Monoclonal Antibodies. Front Immunol. 2020 Aug 18;11:1951. doi: 10.3389/fimmu.2020.01951. PMID: 33013848; PMCID: PMC7461797.

[23] Brun MK, Goll GL, Jørgensen KK, Sexton J, Gehin JE, Sandanger Ø, Olsen IC, Klaasen RA, Warren DJ, Mørk C, Kvien TK, Jahnsen J, Bolstad N, Haavardsholm EA, Syversen SW. Risk factors for anti-drug antibody formation to infliximab: Secondary analyses of a randomised controlled trial. J Intern Med. 2022 Sep;292(3):477-491. doi: 10.1111/joim.13495. Epub 2022 Apr 26. PMID: 35411981; PMCID: PMC9545769.

[24] Hanauer S, Wagner C, Bala M. Incidence and importance of antibody responses to infliximab after maintenance or episodic treatment in Crohn's disease. Clinical Gastroenterology and Hepatology, 2, 542-553

[25] St-Pierre, J., Shafrir, A., & Rubin, D. T. (2024). Interrupting inflammatory bowel disease therapy: why, who, when and how to consider medication holidays. *Expert Review of Gastroenterology & Hepatology*, *18*(10), 587–596. https://doi.org/10.1080/17474124.2024.2412048

[26] https://www.dermatologytimes.com/view/biologic-holiday-question-risk-management

[27] Rubin DT. Restarting Biologic Agents After a Drug Holiday. Gastroenterol Hepatol (N Y). 2019 Nov;15(11):612-615. PMID: 31802986; PMCID: PMC6883732.

[28] Chatlani S. States struggle to help patients navigate insurance hurdle known as 'step therapy.' West Virginia Watch. Published June 14, 2024. Accessed May 4, 2026. https://westvirginiawatch.com/2024/06/14/states-struggle-to-help-patients-navigate-insurance-hurdle-known-as-step-therapy/.

[29] Step Therapy. Arthritis Foundation. Accessed May 4, 2026. https://www.arthritis.org/advocate/issue-briefs/step-therapy.

therapy, the child's symptoms were completely resolved. Despite this success, the child's insurer is now requiring step therapy, demanding the patient switch to one of three alternatives before continuing coverage:

- Lactulose — A less effective laxative than what this child has already tried and failed.
- Lubiprostone — Not FDA-approved for children. A clinical trial of more than 600 pediatric patients showed no benefit over placebo.
- Trulance (plecanatide) — Not FDA-approved for children, and no completed pediatric clinical trials exist.

Complying with this requirement would mean taking a 7-year-old off a medication that works and forcing the child onto treatments that are either proven ineffective in children or completely untested in children, causing weeks to months of unnecessary suffering, missed school, and risk of complications.

We urge CMS to undertake rulemaking requiring new payers to apply the previous payer's determination that a patient has satisfied step therapy and to grant immediate access to the prescribed medication. Additionally, CMS' rule should require insurance plans to recognize the completion of their own step-therapy process across multiple plan years or previous coverage approvals, and a new payer should be required to honor a prior payer's step-therapy determination or continuation approval.

We recommend that this requirement clarify standards for patient eligibility for continuity in coverage. We believe these standards, at a minimum, need to cover the following circumstances:

- Mandate patient eligibility for continuity in coverage by their new payer, even if the prior payer required fewer steps than the new payer.
- Mandate that insurance programs must provide a continuity of coverage for their existing patients, even if the payor expands or alters their fail-first protocols.
- Mandate patient eligibility for continuity in coverage by their new payer — and with an existing payor — even if the new fail-first timelines (e.g., must use first-line drug for 6 months) are longer than those required by their prior plan.
- Mandate patients' eligibility for continuity in coverage by their new payer — and for existing patients to maintain continuity — even if the new plan's preferred treatment(s) differ from the prior plan, provided that the treatments are within the same therapeutic class.

WAIVER OF STEP THERAPY FOR 'UNDERWATER' BIOLOGICS

Physician practices are reporting that certain physician-administered biosimilars are now effectively "underwater," meaning they are reimbursed at rates below their acquisition cost. Large manufacturer rebates have artificially lowered the average sales price (ASP), which serves

as the basis for physician reimbursement. This sharp decline in ASP has made it financially unsustainable for practices to purchase and administer these biosimilars at current Medicare reimbursement levels.

This challenge is exacerbated by MA plans' step-therapy requirements that mandate use of these unaffordable biosimilars before patients can access alternative options. When physicians are unable to absorb financial losses or refer patients to hospital settings, access can be delayed or denied entirely. Further, these challenges undermine the long-term sustainability of the biosimilar market and diminish the value these therapies were intended to bring.

To address the reimbursement and access challenges associated with physician-administered biosimilars in the Medicare program, **we support the establishment of a formulary adequacy standard in MA, requiring that any biosimilar placed in a fail-first position be reasonably available to network providers and, if not, that plans permit timely access to an alternative biosimilar or the reference biologic without additional utilization management, including step therapy. We believe CMS has the authority to establish a formula adequacy standard, and, as such, we ask that the Agency act expeditiously to address this access to care barrier.**

CONCLUSION

Medical decisions should remain in the hands of health care providers and their patients, not insurance companies. For millions of Americans living with chronic digestive illnesses, we urge CMS to protect patients by reining in aggressive PA and step-therapy tactics, streamlining PA processes by increasing the interoperability of systems used across the health care industry, and by requiring transparency by payers in the use of PA.

Should you have any questions or require additional information, please contact the following organizational representatives:

American Association for the Study of Liver Diseases — Matthew D'Uva, CEO, mduva@aasld.org
American College of Gastroenterology — Brad Conway, Vice President, Public Policy & Reimbursement, BConway@gi.org
American Gastroenterological Association — Kathleen Teixeira, Vice President, Advocacy and Practice, kteixeira@gastro.org
American Society for Gastrointestinal Endoscopy —Lakitia Mayo, Chief Policy and Member Engagement Officer, lmayo@asge.org
Crohn's & Colitis Foundation — Erin McKeon, Director, Federal Advocacy, emckeon@crohnscolitisfoundation.org
Digestive Health Physicians Association — Andrew Sousa, Executive Director, andrewsousa@dhpassociation.org
North American Society for Pediatric Gastroenterology, Hepatology and Nutrition — Camille Bonta, Policy Advisor, cbonta@summithealthconsulting.com

Sincerely,

Saul J. Karpen, MD, PhD, FAASLD
Present, American Association for the Study of Liver Diseases

William D. Chey, MD, MACG
President, American College of Gastroenterology

Byron Cryer, MD, AGAF
President, AGA Institute

Jonathan Cohen, MD, MASGE
President-Elect American Society for Gastrointestinal Endoscopy

Laura D. Wingate
Chief Education, Support, & Advocacy Officer
Crohn's & Colitis Foundation

Naresh Gunaratnam, MD
President, Digestive Health Physicians Association

Vicky Ng, MD
President, North American Society for Pediatric, Gastroenterology, Hepatology and Nutrition