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ABC MISSION:

To promote the prevention and treatment of cardiovascular disease including stroke, in Blacks and other minorities and to achieve health equity for all through the elimination of disparities.

February 13, 2023

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Hubert H. Humphrey Building, Room 445-G
200 Independence Avenue, SW
Washington, DC 20201

Submitted via [regulations.gov](https://www.regulations.gov)

Dear Administrator Brooks-LaSure:

The Association of Black Cardiologists (ABC) appreciates the opportunity to provide comment on several policies included in the Centers for Medicare and Medicaid Services (CMS) proposed rule *Contract Year 2024 Policy and Technical Changes to Medicare Advantage (MA) Program (Part C) and Medicare Prescription Drug Benefit (Part D), etc.* [CMS-4201-P]. ABC offers comment on the following sections of the rule:

- Utilization Management Requirements: Clarifications of Coverage Criteria for Basic Benefits and Use of Prior Authorization, Additional Continuity of Care Requirements, and Annual Review of Utilization Management Tools
- Review of Medical Necessity Decisions
- Changes to an Approved Formulary

Founded in 1974, the ABC is a nonprofit organization with a national and international membership of more than 2,000 cardiovascular specialists, cardiologists-in-training and other health professionals, as well as community based 'lay' advocates and corporate/institutional members. The ABC is dedicated to eliminating disparities related to cardiovascular disease for all people of color and adheres to the vision that all people regardless of race, ethnicity or gender should benefit equally from reduction in the frequency, duration and impact of diseases of the heart and blood vessels.

UTILIZATION MANAGEMENT REQUIREMENTS

Despite declines in cardiovascular disease mortality over several decades, significant disparities continue to exist when comparing the health status of black individuals to whites — disparities that can be largely attributed to cardiovascular-related mortality.

As highlighted in a [2019 ABC report](#), underserved and minority patients face unique challenges to cardiovascular care and treatment that impact their health outcomes. The ability to access new treatments is often hampered by utilization management processes that are put in place by insurers. In particular, the need for prior authorization (PA) – the approval from an insurer that may be required before patients receive a device, intervention, or medical treatment to be covered by that insurer — has been a barrier to treatment and a burdensome process for physicians and other providers. Representatives from ABC, in conjunction with a multi-sector group of experts, hypothesized that lower resource levels at cardiology practices with a majority of patients from underserved and minority populations may pose a unique barrier to responding to PA needs for these patients, further fostering existing treatment disparities.

The 2019 report highlighted the findings of a survey the ABC conducted in partnership with the American College of Cardiology in February 2018 that asked physicians about barriers encountered in prescribing the newest evidence-based therapy for cardiovascular care. Data from that survey show that almost all physicians (98%) experience a barrier when prescribing new evidence-based therapy, with the most prevalent barriers being cost issues (78%) and prior authorization documentation/administrative burden (75%). These findings are consistent with a more [recent survey](#) of physicians conducted by the American Medical Association (AMA) that found PA imposes substantial burden on physician practices and negatively affects patient care and outcomes.

While the impacts of PA, including delays in care, patient confusion and treatment discontinuation, are not uniquely felt by minority populations, they may create the perception among minority patients that they do not deserve the medical care recommended by their physicians. Prior authorization is a barrier to care that disproportionately affects minority and other vulnerable populations, may further limit treatment for groups that are already under-treated and must be meaningfully addressed by policymakers.

Clinical Coverage Criteria

ABC supports better guardrails to ensure minimum coverage requirements are met by MA plans and that MA plan processes and policies do not deny or restrict coverage of basic benefits to their enrollees. We therefore ask CMS to finalize the following proposals, but to first strengthen them by extending the proposed clinical validity and transparency of coverage criteria policies into the area of prescription drugs:

- codify existing standards for coverage criteria to ensure that basic benefits coverage for MA enrollees is no more restrictive than traditional Medicare;
- prohibit MA organizations from denying coverage of an item or service based on internal, proprietary, or external clinical criteria not found in traditional Medicare coverage policies;

- when coverage criteria are not fully established in applicable Medicare statute, regulation, National Coverage Determination (NCD) or Local Coverage Determination (LCD), an MA plan may create internal coverage criteria that are based on current evidence in widely used treatment guidelines or clinical literature that is made publicly available;
- the development of internal policies must follow similar rules that CMS and MACs follow when creating NCDs or LCDs. The process must also be transparent and based on current evidence in widely used treatment guidelines or clinical literature; and
- prohibit MA plans from using prior authorization to delay or discourage care.

With regard to the definition of “widely used treatment guidelines,” we support that CMS expects those guidelines be developed by organizations representing clinical medical specialties for the treatment of specific diseases or conditions. According to the [AMA survey](#), roughly 30 percent of physicians report that health plans’ PA criteria are rarely or never based on evidence-based guidelines and/or guidelines from national medical specialty societies. We suggest that better MA plan accountability is needed in this regard. Moreover, ABC proposes that where there is disagreement in specific medical specialty guidelines, plans should utilize the full compendium of evidence-based guidelines in the literature for developing criteria.

Continuity of Coverage

ABC asks CMS to finalize the following proposals to protect patients, especially those with chronic conditions, from care interruptions, treatment delays, and unanticipated medical costs:

- All approved prior authorizations must be valid for the duration of the entire approved prescribed or ordered course of treatment or service (including scheduled procedures regardless of whether there are specific visits or activities leading up to the procedure).
- MA organizations offering coordinated care plans must have, as part of their arrangements with contracted providers, policies for using prior authorization that provide for a minimum 90-day transition period for any ongoing course(s) of treatment when an enrollee has enrolled in an MA coordinated care plan after starting a course of treatment, even if the course of treatment was for a service that commenced with an out-of-network provider.

ABC also supports codification of the following current Part D plan policies that strengthen protections for continuity of prescription drug therapy:

- Part D plans must provide an appropriate transition for patients facing a new quantity limit on a formulary medication.
- If a Part D sponsor has access to prior drug claims history for the enrollee (through an affiliated plan or otherwise), the sponsor must use a minimum 108-day claims history look-back period to determine whether a pharmacy claim represents a new prescription which would not require a transition fill, or ongoing drug therapy which would require a transition fill.
- If a Part D sponsor does not have access to prior claims history for the enrollee and cannot determine at point-of-sale whether a pharmacy claim represents a new prescription or

ongoing therapy, the sponsor must treat the prescription as ongoing therapy which requires a transition fill.

- Part D sponsor's transition policies and procedures must include assurances that the Part D sponsor's P&T Committee has reviewed, provided recommendations as warranted, and approved the plan's transition policies and procedures.
- Part D patients experiencing a level of care change, such as admission or discharge from a hospital, must be provided with the plan's transition process for ongoing prescription drug therapy.

Further, for patients with ongoing medication therapy, Part D plans' PA approvals must remain valid for the duration of prescribed course of treatment.

REVIEW OF MEDICAL NECESSITY DECISIONS

ABC supports CMS' proposal to require that during initial medical necessity determinations, the physician or other appropriate health care professional who conducts the review must have expertise in the field of medicine that is appropriate for the item or service being requested before the MA organization issues an adverse determination. However, we additionally request that reviews be conducted by a licensed physician in the state where care is being provided.

CHANGES TO AN APPROVED FORMULARY

Proposed Provisions for Approval of Formulary Changes

CMS proposes a definition of negative formulary changes as the following changes with respect to a Part D drug: (1) removing the drug from a formulary; (2) moving the drug to a higher cost-sharing tier; or (3) adding or making more restrictive prior authorization, step therapy, or quantity limits requirements for the drug.

ABC supports this definition and CMS' proposal to codify existing policies with respect to negative changes to approved formularies, including that:

- Part D plan sponsors must not implement non-maintenance changes until they receive notice of approval from CMS;
- affected enrollees are exempt from approved non-maintenance changes for the remainder of the contract year; and
- Part D sponsors are prohibited from making certain negative formulary changes between the beginning of the annual election period until 60 days after the beginning of their contract year.

To ensure that Part D beneficiaries and their physicians receive adequate notice of formulary changes, and to protect against potential care disruptions, CMS should require at least a 60-day notice period for maintenance and non-maintenance negative formulary changes.

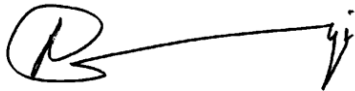
IMMEDIATE FORMULA SUBSTITUTIONS

CMS proposes to allow Part D plans to immediately substitute an interchangeable biological product for its corresponding reference product, expanding on current policy that allows plans to immediately remove a brand drug from their formularies and substitute a newly released generic equivalent. The use of biologics is limited in the treatment of cardiovascular disease; however, other diseases for which biologics are the primary treatment may also be risk factors for cardiovascular effects. As such, ABC is very concerned about the proposed requirement of advance general notice of immediate substitutions, followed by written notice to affected enrollees as soon as possible, but by no later than the end of the month following any month in which a change takes effect. Part D plans should be required to immediately notify both impacted patients and prescribers when an “immediate substitution” takes effect for an interchangeable biological product rather than permitting a communication delay that could reach up to two months.

CONCLUSION

ABC is grateful CMS is attempting to create necessary guardrails for prior authorization and other utilization management tactics used by MA and Part D plans. But, as our above comments highlight, there is room for even stronger rules and regulations to ensure that medically necessary care or therapy recommended by a treating physician is accessible to all patients, not just those who have the resources to navigate care denials and appeals. Improving health equity means ensuring that permissible prior authorization and utilization management do not disadvantage minority and/underserved populations and widen health disparities, and we hope that you will keep this a central focus as the Agency works to finalize these proposals. Should you have questions or require additional information, please contact Camille Bonta, ABC policy advisor, at cbonta@summithealthconsulting.com or (202) 320-3658.

Sincerely,



Anekwe E. Onwuanyi, MD
President
Association of Black Cardiologists



Barbara A. Hutchinson, MD, PhD
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