August 30, 2022

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-4203-NC
P.O. Box 8013
Baltimore, MD 21244-8013

Re: Seeking Input on Various Aspects of the Medicare Advantage Program (CMS-4203-NC)

Dear Administrator Brooks-LaSure,

The Alliance for Aging Research (“Alliance”) appreciates the opportunity to comment on ways to improve the Medicare Advantage (MA) program. The Alliance is the leading nonprofit organization dedicated to accelerating the pace of scientific discoveries and their application to vastly improve the universal human experience of aging and health.

The Alliance supports CMS’ Strategic Vision and has long supported ensuring that all Medicare beneficiaries have access to the medical care they need. Relatedly, many MA participants receive a wider range of medical benefits – such as vision, dental, and other benefits – that are vital to ensuring good health yet are not covered by the fee-for-service (FFS) benefit. At the same time, there are opportunities to improve the program to ensure all patients have equitable access and promote regular preventative care and diagnostics for the aging population. We thank CMS for the opportunity to provide targeted feedback on initiatives that can support these aims.

Health Equity

Question A1: What steps should CMS take to better ensure that all MA enrollees receive the care they need?

Quality Adjusted Life Year
It is imperative that all MA plans be barred from using the Quality-Adjusted Life Year (QALY) or similar discriminatory metrics when making coverage and formulary placement determinations. In 2010, the Affordable Care Act included provisions barring the use of QALYs by the Patient-Centered Outcomes Research Institute and by Medicare to determine coverage, reimbursement, and incentive programs. However, while

the FFS program is prohibited from using QALYs, private payers – including MA plans – frequently utilize QALYs to determine which therapeutics are covered and where the product should be placed on a formulary. While proponents of the QALY, such as the Institute for Clinical and Economic Review (ICER), assert that the formula is an agnostic method for determining the relative value of a care intervention, the underlying methodology has repeatedly been shown to discriminate against individuals with a disability and older adults. Since 2019, the National Council on Disability (NCD), an independent federal agency, has advised against the use of discriminatory price-setting methodologies such as QALY in federally funded programs because their use undermines the Affordable Care Act (ACA) and major U.S. disability and civil rights laws. Earlier this year, the NCD’s 2022 health equity framework put a finer point on the importance of this and called for a “blanket [legislative] prohibition” on the use of QALYs by “any federal agency.” Last fall, more than 130 organizations called on Congress to reject drug proposals that use the QALY methodology or similar value assessment frameworks, stating, “As Medicare is the primary source of health insurance for older adults and people with disabilities, utilizing QALYs or similar metrics in pricing would be particularly harmful to the very groups the program is intended to serve.”

Managed care organizations (MCOs) are frequently utilizing ICER’s reports. A 2020 analysis of data from payers and other health care decision makers collected from FormularyDecisions and published in the Journal of Managed Care & Specialty Pharmacy found that MCOs represented 39 percent of active users that accessed ICER reports within the FormularyDecisions platform. Of the MCO users that provided responses, 74 percent indicated they used ICER evaluations for decision-making, and a majority (61.2 percent) indicated they have used or will use an ICER report in their formulary review. Of those MCOs who used ICER assessments to support clinical decision-making, 35.0 percent indicated they were used as a primary source of evidence to support their evaluation and pharmacy and therapeutics (P&T) preparations, 52.2 percent as a secondary source of evidence, 44.6 percent to assist in determining product affordability, and 42 percent to inform or validate their own research and analysis.

The end result of the use of the QALY is that therapeutics that treat conditions disproportionately impacting individuals with a disability and older adults – the very two populations for which Medicare provides coverage – are systemically viewed as having a lower value. As a result, therapeutics that treat these conditions are more likely to be subject to non-coverage or non-preferred formulary placement in comparison to conditions impacting other population groups. Insurers should be encouraged to collaborate in the development of methods to assess the value of treatments that better acknowledge the complexity of healthcare coverage decisions and elevate the outcomes that matter to patients and their families.

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Risk Adjustment
Medicare Advantage plans use hierarchical condition category codes (HCCs), also known as risk coding, to estimate future health care costs for patients. Such coding is discriminatory, as the risk scores use health costs as the measure for health need. A 2019 study examined risk coding and found that Black patients assigned the same risk score are sicker than white patients. This is Black beneficiaries have lower access to care and, as a result, lower health utilization which artificially depresses their health costs. While this metric was intended to be race-blind, according to the study this effect reduced the number of Black patients identified for extra care by more than half—collectively, Black patients suffered from 48,772 additional chronic diseases compared to their white counterparts.

These equity concerns are exacerbated by CMS’s addition in 2020 of two additional HCCs for dementia—dementia with complications and dementia without complications—for use in MA plans. Individuals with Alzheimer’s already are subject to incomplete coverage due to the recent National Coverage Determination for monoclonal antibodies targeting amyloid for the treatment of Alzheimer’s disease. These HCCs pose an unacceptable additional risk of lack of coverage for Alzheimer’s patients and specifically patients of color. It is CMS’ responsibility to provide coverage for all underserved patients in MA plans. We encourage CMS to further examine the impact of the use of HCCs in MA plans and assess whether changes are needed in methodology or practice delivery to support equitable patient outcomes.

Protecting Alzheimer’s Patients
According to Meyers et al. patients experiencing Alzheimer’s disease and related dementias (ADRD) are less likely to switch between various MA plans, but substantially more likely to disenroll from MA plans altogether in favor of traditional Medicare coverage. This is consistent with other recent findings which indicate that MA beneficiaries with greater needs disenroll at higher rates. The authors posit that the high disenrollment rate from MA plans indicate that ADRD patients are not being optimally served by their MA plan.

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8 Meyers, D; Belanger, E; McHugh, J; Rahman, M; and Mor, V. “Analysis of drivers of disenrollment and plan switching among medicare advantage beneficiaries.” JAMA Intern Med. 25 Feb 2019. [https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2725083](https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2725083)
MA plans may not work well for ADRD patients for a variety of reasons, including narrower provider networks, less access to high-quality nursing homes, hospitals, and home health agencies than traditional Medicare beneficiaries. These problems are a significant concern for ADRD patients when considering MA plans. Additionally, MA plans should be tailored to ADRD patients by covering wraparound care, a standard of care for ADRD patients in which the care team creates a highly individualized plan for the person with dementia and family. CMS has allowed for companies that offer MA plans to create and offer Chronic Disease Special Needs Plans (SNPs) to serve the unique needs of each population. However, it is difficult to find specific information on these SNPs and the authors note that during their study period (2014-2015) there was only one SNP dedicated to patients with ADRD. CMS must encourage further development of these SNPs and better methods for communicating the availability of these programs to patients who would benefit from them.

CMS should work to ensure that individuals diagnosed with ADRD have access to a robust infrastructure of supports to ensure that they receive the care they need from their full care team, are supported in selecting the correct MA plan for their specific circumstances, and that their out-of-pocket (OOP) costs are as low as possible.

Annual Wellness Visit (AWV)
At present, there is low uptake of the AWV, which provides a yearly check in to develop a personalized care plan, including scheduling appropriate screenings given a person’s health condition, age, and medical history. An important part of the AWV is a cognitive assessment to determine if there are indicators of dementia. Beneficiaries enrolled in MA plans are more likely to utilize the AWV than FFS beneficiaries. Jacobsen et al. conducted a study which looked at the AWV in MA plans. They found that overall, approximately one-half of beneficiaries surveyed reported having an annual wellness visit, and fewer than one-third reported having a structured cognitive assessment. Compared with FFS enrollees MA enrollees were nearly 20 percentage points more likely to report that they utilized the AWV and 8.6 percentage points more likely to report that it included a structured cognitive assessment compared with fee-for-service (FFS) enrollees.

10 Meyers, D; Mor, V; and Rahman, M. “Medicare advantage enrollees more likely to enter lower-quality nursing homes compared to fee-for-service enrollees.” Health Aff (Milwood). 18 Jan 2018. https://pubmed.ncbi.nlm.nih.gov/29309215/
11 Meyers, D; Trivedi, A; Mor, V; and Rahman, M. “Comparison of the quality of hospitals that admit medicare advantage patients vs traditional medicare patients.” JAMA Netw Open. 15 Jan 2020.
12 Schwartz, M; Kosar, C; Mroz, T; Kumar, A; and Rahman, M. “Quality of home health agencies serving traditional medicare vs medicare advantage beneficiaries.” JAMA Netw Open. 4 Sep 2019.
14 Jacobsen, M; Thunell, J; and Zissimopoulos, J. “Cognitive Assessment at Medicare’s Annual Wellness Visit In Fee-For-Service And Medicare Advantage Plans”. Health Affairs. Nov 2020.
While this is a marked improvement, it is vital to ensure that every patient utilizes the AWV and receives a cognitive assessment. A study by Lind et al.\(^\text{15}\) found that dementia diagnosis rates increased with AWV implementation with heterogenous effects by race and ethnicity—Asian and Hispanic populations were found to get the most benefit from utilization of the AWV. This is noteworthy as Hispanics are 1.5 times more likely than whites to have ADRD but are only .18 percent more likely to be diagnosed,\(^\text{16}\) and Asian Americans are relatively less likely than other groups to have Alzheimer’s disease which can make it harder for individuals or families to recognize the symptoms and seek professional care.\(^\text{17}\) Promoting awareness of the AWV among both patients and physicians and increasing mechanisms or incentives for utilization of AWV must be a priority for all MA plans in order to ensure proper detection and diagnosis of cognitive impairment.

**Improving Data Collection in Electronic Health Records (EHR)**

According to Maserejian et al.,\(^\text{18}\) only 11 percent of dementia patients and 24 percent of Alzheimer’s disease patients had any type of cognitive measure documented in their medical records five years prior to diagnosis. At present, there is no easy way to report whether a physician has performed cognitive screening on a patient in the EHR. Implementing a systematic mechanism to ensure such reporting would enhance the standard of care patients receive by ensuring that a beneficiary’s full care team is aware of the course and possible prognosis of a patient’s condition and thus fully equipped to provide optimal treatment. The Alliance proposes that all EHR technology used by MA plans include a checkbox list to indicate which cognitive screen has been performed and whether the result indicated a need for additional follow-up, thereby reinforcing the expectation that such screenings are standard practice and expected as part of each visit. This follows the conclusions found by the same study, which reported “Extensive missing cognitive data and differences in the availability of cognitive measures by race, age, and socioeconomic factors hinder patient care and limit utility of EHR for dementia research. Structured fields and prompts for cognitive data [such as the cognitive screening] inputs at the point of care may help address these gaps.”

**Question A.11: How are MA plans currently using MA rebate dollars to advance health equity and to address SDOH? What data may be helpful to CMS and MA plans to better understand those benefits?**

**Social Determinants of Health (SDOH)**

Starting in 2019, CMS provided MA plans the option to offer community-based services to address social determinants of health (SDOH) for chronically ill beneficiaries. Some MA plans provide benefits that help to address SDOH that contribute to inequitable health outcomes including meal delivery services, adult day care, home safety improvements, personal home helpers, and transportation.\(^\text{19}\) These benefits help patients who

\(^{15}\) Lind, K; Hildreth, K; Lindrooth, R; Morrato, E; Crane, L; and Perraillon, M. “The effect of direct cognitive assessment in the Medicare annual wellness visit on dementia diagnosis rates.” Health Serv Res. 22 Jan 2021. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7968942/


might otherwise not have the resources and access necessary to utilize these mechanisms of care. The provision of such benefits should be broadly encouraged. In addition, MA plans should be incentivized to consider the broad range of social and economic determinants of health for all enrollees. The Office of Disease Prevention and Health Promotion classifies the various elements of SDOH into five categories:\(^\text{20}\) economic stability, education access and quality, healthcare access and quality, neighborhood and built environment, and social and community context. MA plans should work with patients and physicians to ensure that each of these factors are considered in all elements of patient care. Notable examples of this include safe transportation, income, access to nutritious foods, and relief from polluted air and water. MA plans should ensure that patients have access to a physician who speaks a patient’s native language or to a translator for all medical appointments. These examples constitute a small number of ideas for improvement of SDOH benefits within MA, but there are many more that CMS can and should explore.

**Expand Access: Coverage and Care**

**Question B.10: How do MA plans use utilization management techniques, such as prior authorization?**

**What approaches do MA plans use to exempt certain clinicians or items and services from prior authorization requirements? What steps could CMS take to ensure utilization management does not adversely affect enrollees’ access to medically necessary care?**

**Step Therapy**

In 2018 CMS issued new guidance\(^\text{21}\) that allowed MA plans to use step therapy for Part B drugs, citing step therapy as a method to reduce costs and encourage lower drug spending while maintaining access to covered services and medications. This is concerning, as patients with conditions subject to step therapy may experience delays in care that can harm long-term care outcomes, especially for conditions where loss in function may occur as a patient progresses through the “steps.” The Alliance believes that patient-centered care must be the driving factor for care decisions, not utilization mitigation. Decreased patient access to the most appropriate medication for their individual care needs is a significant concern under step therapy. While a less expensive drug may generally work for a certain condition, there are countless factors that can make that drug an incorrect choice for a specific patient, including allergic reactions, patient preference, side effects, and comorbidities. According to Tharp et al.,\(^\text{22}\) patients may also be forced to try and fail the same treatment multiple times if they either move or change their job/insurance coverage. Additionally, a study by Farley et al.\(^\text{23}\) comparing spending on atypical antipsychotics in Georgia and Mississippi Medicaid programs showed that the step-therapy protocol saved Georgia $19.62 per member per month.

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\(^{20}\) Office of Disease Prevention and Health Promotion. “Social Determinants of Health.”
https://health.gov/healthypeople/priority-areas/social-determinants-health


\(^{22}\) Tharp, L and Rothblatt, Z. “Do patients benefit from legislation regulating step therapy?” Cambridge University Press.

\(^{23}\) Farley, J; Cline, R; Schommer, J; Hadsall, R; and Nyman, J. “Retrospective assessment of Medicaid step-therapy prior authorization policy for atypical antipsychotic medications.” Clinical Therapeutics. Aug 2008.
month but increased outpatient service costs by $31.59 per member per month, for a net increased cost of $11.97 per member per month.

Given the limited evidence of savings of step therapy utilization when considering a beneficiary’s total costs – rather than just drug costs – as well as the clinical risk the practice introduces for patients, CMS should reintroduce the ban on step therapy for MA plans. At a minimum, CMS should ensure that the patient protections recommended by the National Health Council in 2018\(^{24}\) are put in place for all participating MA plans. These include:

- Adherence to evidence-based treatment guidelines: Guidelines must be put in place to require step therapy protocols to follow clinical practice guidelines and best practices that have been vetted through the peer review process.
- Protection for mid-treatment patients: Policies must be implemented to ensure that patients who are currently using an effective medication do not have to change medications for any newly implemented step therapy protocols.
- Recognized standard of care: There must be a requirement to start step therapy with the recognized standard of care – even if that recognized standard is not the least-expensive drug.
- A simple and expeditious exceptions and appeals process: Treatment for patients who need a drug higher in the step protocol should not be delayed by a lengthy appeals process.
- Full transparency and oversight: Medicare beneficiaries should know in advance of enrolling in a health insurance plan whether there is a restrictive step therapy clause.

Denial of coverage following an emergency department visit

In recent years, multiple carriers of Medicare Advantage plans have proposed or implemented new claims processing reviews that result in retrospective claims denials for emergency department (ED) care.\(^ {25,26}\) While these reviews have not been focused on MA, CMS should proactively prohibit their use in the program. These practices present patients with an untenable dilemma: understand their plan benefits and diagnose themselves correctly prior to seeking care or risk a substantial emergency room bill with no insurance coverage. While there are care coordination benefits and generally lower costs associated with seeking care from a primary care or regular care provider, patients should not be denied coverage for what the patient believes to be an emergent care need. Importantly, and as we have seen with the COVID-19 pandemic, increased risk of morbidity and mortality is associated with both chronic and acute health conditions when patients avoid the emergency room and delay care.\(^ {27}\)

Current CMS policy does not explicitly prevent retrospective claim denials for ED visits, claiming that hospital services that could have been furnished in a lower cost setting are “medically unreasonable and


\(^ {27}\) Centers for Disease Control and Prevention. “Delay or Avoidance of Medical Care because of COVID-19—Related Concerns.” 11 Sep 2020. https://www.cdc.gov/mmwr/volumes/69/wr/mm6936a4.htm
unnecessary.” We encourage CMS to issue clarifying guidance that prevents MA plans from retrospectively denying claims for ED visits, except in cases of suspected fraud, waste, or abuse. Instead, such insurance coverage decisions must be made based on the assessment of symptoms of the patient when entering the emergency room and clearly communicated with a patient in advance of the services being furnished.

Denial of coverage based on the QALY and similar averaging metrics
As mentioned above in our response to Question A1, the QALY is a harmful and discriminatory metric that does not support CMS’ goal of patient-centered care. It is also not a useful method in determining the value of a drug, as it does not take the full patient perspective into consideration. Efforts to use QALY to deny patient coverage—such as CVS’s recent push, since retracted, in the commercial market to automatically deny drugs that cost more than $100,000/QALY—should explicitly be banned in guidance to MA plans. QALYs fail to account for important variables in costs of care such as a novel therapy’s ability to treat a previously untreatable illness, treatment of symptoms even if the therapeutic is not disease-modifying, ease of regimen compared to alternatively complex treatments, and difficult to capture metrics such as the economic benefit of a healthy population. Value assessment is still a relatively immature field of study and current cost-effectiveness methodologies such as the QALY, ICER’s Equal Value of Life Years Gained metric, disability adjusted life years (DALY), and other similar metrics should not be used to deny patients access to care writ large or used in the development of formularies.

Support Affordability and Sustainability

Question D.1: What policies could CMS explore to ensure MA payment optimally promotes high quality care for enrollees?

Pricing stability for formulary medications in Part D plans
Kaiser Health News has recently highlighted the challenges that beneficiaries face after selecting a health plan, as the cost that plans charge for drugs often change mid-year. List prices charged by pharmaceutical companies do change, often impacting coinsurance amounts that beneficiaries pay. Pricing stability is important to patients. We encourage CMS to evaluate solutions that limit beneficiary price increases to clearly defined periods, such as on a quarterly or a semi-annual basis during a plan year. We also encourage CMS to explore regulatory flexibilities and MA/Pharmacy Benefit Manager (PBM) agreements that could prevent increases in drug costs in excess of the rate of inflation (i.e., an inflationary cap) without appropriate justification, such as a sudden change in production capacity due to a natural disaster. The validity of such justifications could be determined by CMS or through an external arbitration process.

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Services covered under MA plans that should be available to all beneficiaries

There are several supplemental benefits that are currently only available under MA plans that should be available to all FFS beneficiaries. These medically necessary services include dental, vision, and hearing benefits. Other benefits supported in MA plans that should be covered under FFS include enhanced care coordination services and initiatives to address SDOH for chronically ill beneficiaries. While spending on a per beneficiary basis in MA is greater than the average amount spent for an FFS beneficiary, MA plans often offer many benefits that are essential for person-centered care and ensuring health but that are not reimbursable through the FFS program. We encourage the agency and policymakers to consider these important contextual considerations as they evaluate payment rates for MA plans. Further, while adding benefits to FFS coverage would require legislative action, CMS should investigate all available tools that can be used to ensure that more patients receive these benefits.

Contact information

The Alliance thanks CMS for the opportunity to comment on this issue. If you have any questions or would like to follow up on the items discussed in our comments, please contact Adina Lasser, Public Policy Manager, at alasser@agingresearch.org. We look forward to working with you.

Sincerely,

Michael Ward
Vice President of Public Policy and Government Relations

Adina Lasser
Public Policy Manager