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August 31, 2022

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
200 Independence Avenue S.W.
Washington, DC 20201

Re: CMS-4203-NC — Request for Information: Medicare Advantage Program

Dear Administrator Brooks-LaSure:

As the premier trade association representing the manufacturers of medical imaging equipment, radiopharmaceuticals, contrast media, and focused ultrasound devices, the Medical Imaging & Technology Alliance (MITA) is submitting the following comments on the referenced request for information (RFI) from the Centers for Medicare & Medicaid Services (CMS) regarding the Medicare Advantage (MA) program.

In this RFI, CMS is seeking public input regarding various aspects of the MA program, including on advancing health equity, expanding access to coverage and care, driving innovation to promote person-centered care, support affordability and sustainability, and engaging partners.

In recent years, MITA member companies have introduced innovative technologies to the market, including low-dose CT, high-intensity focused ultrasound (HIFU), novel imaging agents, and advanced AI algorithms. These technologies play an essential role in our nation's health care infrastructure and the care pathways of screening, staging, evaluating, managing, and effectively treating patients with cancer, heart disease, neurological degeneration, COVID-19, and numerous other medical conditions. Equitable Medicare beneficiary access to these technologies will depend on appropriate coverage in both traditional fee-for-service (FFS) Medicare, as well as in the Medicare Advantage program.

According to a July 2021 MedPAC report, nearly half of all Medicare beneficiaries are enrolled in MA plans.[1] That number is expected to quickly exceed 50% if the trend continues.[2] As more Medicare beneficiaries enroll in MA plans, it will be critical to ensure that they are eligible for the same care as beneficiaries enrolled in FFS Medicare. We are concerned, however, that this is not always the case and that more Medicare beneficiaries will be denied coverage for reasonable and necessary care in the future. In fact, an April 2022 report from the Office of the Inspector General (OIG)[3] raised concerns about certain MA plans impeding beneficiary access to reasonable and necessary care. Given the rapid

[1] https://www.medpac.gov/wp-content/uploads/2022/07/July2022_MedPAC_DataBook_SEC_v2.pdf.
[2] https://www.medpac.gov/wp-content/uploads/2021/10/MA-status-MedPAC-Jan22.pdf.
[3] https://oig.hhs.gov/oei/reports/OEI-09-18-00260.pdf

enrollment growth of MA plans, greater oversight and accountability will be necessary to ensure that Medicare beneficiaries are receiving the care they need.

Currently, MA plans are required to cover all of the items and services covered by traditional FFS Medicare Part A and Part B. Coverage should be comparable whether a beneficiary is enrolled in traditional Medicare or Medicare Advantage.

Medicare Advantage plans, however, are allowed to implement utilization management processes, such as prior authorization. Prior authorization requires that healthcare providers submit a request to the MA plan before an item or service can be provided to a patient. As the OIG found in its April 2022 report, this can result in significant administrative burdens being placed on healthcare providers and patients and result in denial of otherwise reasonable and necessary care for patients that would have been covered under FFS Medicare.[4] According the report, MA plans inappropriately denied 13% of prior authorization requests that met Medicare coverage rules. Given the increasing share of Medicare beneficiaries covered by MA plans, this is not an insignificant number of denials.

Of particular concern to MITA, is that advanced imaging services—including MRI and CT—are among the most commonly denied requests for prior authorization by MA plans.[5] In many cases, MA plans inappropriately deny coverage for advanced imaging unless a less advanced imaging scan was performed first. Medicare covers MRI[6] and CT[7] services when they are medically necessary and appropriate for the beneficiary. We are also aware that other advanced imaging services such as PET and SPECT, although not specifically called out in the report, face the same challenges. Similarly, Medicare covers PET and SPECT as medically necessary and appropriate, yet, provision of these services is often inappropriately denied by MA plans. Inappropriate denial of these reasonable and necessary imaging services means that beneficiaries will not receive the care they need, potentially resulting in a missed or delayed diagnosis.

Inappropriate prior authorization requirements are also being applied to items and services covered under Medicare Coverage with Evidence Development (CED) and investigational device exemption (IDE) policies. Medicare CED and IDE policies are types of coverage that CMS uses while data and evidence are still being generated. These coverage policies require beneficiaries to participate in a CMS-approved clinical trial or other form of study, such as a registry, for certain devices and related care to be covered. There are strict enrollment criteria for beneficiaries receiving items or services covered under these policies. Unfortunately, MA plans often impose inappropriate additional prior authorization requirements that can deny or delay coverage for extended periods of time. This means that otherwise eligible beneficiaries are not receiving the care they need when they need it.

MITA has faced challenges with MA plans appropriately covering CED services. PET scans that are used to assess buildup of amyloid plaque in the brain and help physicians diagnose Alzheimer's disease are covered under a CED. The IDEAS trial was launched to meet the requirements of this CED, enrolling thousands of patients throughout the country. Medicare beneficiaries enrolled in MA plans faced unnecessary challenges to enrolling in the IDEAS CED. In many cases, even when CED inclusion criteria were met, prior authorizations were denied by MA plans. This means that a significant amount of Medicare beneficiaries were *de facto* excluded from this important clinical trial.

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[4] ibid
[5] ibid
[6] CMS, National Coverage Determination (NCD) for Magnetic Resonance Imaging (220.2), April 10, 2018. https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?ncdid=177&ncdver=6&bc=AAAAAAAAAAQAA&=
[7] CMS, National Coverage Determination (NCD) for Computed Tomography (220.1), March 12, 2008. https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=176

As new technologies come to market under CED coverage, Medicare will need to exert greater oversight over MA plans to ensure that CED policies are being properly implemented Additional education is also need for claims adjudication of CED claims with the MA plans. When prior authorization denials are resolved, commonly the subsequent claims are denied. More education is needed by CMS with MA plans to ensure there are no erroneous denials of either prior authorizations or claims for those beneficiaries who qualify for coverage under the CED.

Further, most items and services with an established Medicare benefit category are covered in the absence of a formal National Coverage Determination (NCD) or Local Coverage Determination (LCD). The majority of services delivered to Medicare beneficiaries are paid under the "reasonable and necessary" criteria, with medical necessity documented in the patient's medical record.

Given the absence of a specific formal coverage policy in effect in a particular state for many items and services, MA plans often substitute their own commercial plan coverage policies. These commercial coverage policies are often more restrictive and deny Medicare beneficiary access to the same items and services that would be available to them under traditional FFS Part A and Part B. In cases where an MA plan substitutes its own commercial coverage policy, CMS requires the plan to "provide CMS an objective evidence-based rationale relying on authoritative evidence" for their coverage policies."[8] Despite this, there is often insufficient transparency into the evidence considered in development of these policies. MA plan enrollees and other stakeholders are generally not afforded the opportunity to engage in a public policy development process concerning coverage like what occurs for Medicare Part A and Part B. It is also not clear that commercial coverage policies are appropriate for the Medicare population.

CMS should exert greater oversight over MA plans to ensure that Medicare beneficiaries are receiving the reasonable and necessary care they need, when they need it. The OIG report outlines three recommendations for CMS:

1. Issue new guidance on the appropriate use of MAO clinical criteria in medical necessity reviews
2. Update its audit protocols to address the issues identified in this report, such as MAO use of clinical criteria, and/or examine particular service types
3. Direct MAOs to take additional steps to identify and address vulnerabilities that can lead to manual review errors and system errors

MITA supports these recommendations. Oversight is needed to ensure that prior authorization policies are not resulting in denial of reasonable and necessary care or placing excess administrative burden on healthcare providers and their patients. CMS should exert greater oversight over MA plans to ensure that their commercial coverage policies are sufficiently transparent and that appropriate evidence has been considered. The Agency should also consider significant financial penalties for noncompliant MA plans.

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[8] Medicare Managed Care Manual, § 90.5.

If you have any questions, please contact Peter Weems, Senior Director of Policy & Strategy, at 703-841-3238 or by email at pweems@medicalimaging.org.

Sincerely,

Patrick Hope
Executive Director, MITA

MITA is the collective voice of medical imaging equipment and radiopharmaceutical manufacturers, innovators and product developers. It represents companies whose sales comprise more than 90 percent of the global market for medical imaging technology. These technologies include: magnetic resonance imaging (MRI), medical X-Ray equipment, computed tomography (CT) scanners, ultrasound, nuclear imaging, radiopharmaceuticals, and imaging information systems. Advancements in medical imaging are transforming health care through earlier disease detection, less invasive procedures and more effective treatments. The industry is extremely important to American healthcare and noted for its continual drive for innovation, fast-as-possible product introduction cycles, complex technologies, and multifaceted supply chains. Individually and collectively, these attributes result in unique concerns as the industry strives toward the goal of providing patients with the safest, most advanced medical imaging currently available.