



May 29, 2024

The Hon. Chiquita Brooks-LaSure
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-4207-NC
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: Medicare Program; Request for Information on Medicare Advantage Data

Dear Administrator Brooks-LaSure:

Haystack Project and the CLL Society appreciate the opportunity to provide comments to the Centers for Medicare & Medicaid Services' (CMS') Request for Information on Medicare Advantage Data.

Haystack Project is a 501(c)(3) non-profit organization enabling rare and ultra-rare disease patient advocacy organizations to coordinate and focus efforts that highlight and address systemic reimbursement obstacles to patient access unique to rare diseases or particularly pronounced in extremely rare diseases. Haystack Project is committed to educating policymakers and other stakeholders about the unique circumstances associated with extremely rare conditions with respect to product development, commercialization, and fair access to care. Our core mission is to evolve health care payment and delivery systems with an eye toward spurring innovation and quality in care toward effective, accessible treatment options for all Americans living with or caring for someone with a rare or ultra-rare condition.

Background

Individuals with rare and ultra-rare conditions often require multiple, and potentially high-cost medications, as well as care from highly specialized clinicians. Approximately 7,000 rare diseases have been identified to date, 90-95% of which have no FDA-approved treatment.

In addition to high health care costs, rare disease patients face substantial challenges from symptom emergence through treatment or management of their condition. In 2021, the Government Accountability Office (GAO) compiled a report to Congress entitled “RARE DISEASES: Although Limited, Available Evidence Suggests Medical and Other Costs Can Be Substantial.” The report assessed the challenges rare disease patients face accessing diagnostic and treatment services as well as the personal and economic costs associated with treatment delays. Among its findings, the GAO noted that:

- Rare and ultra-rare disease patients are often unable to access specialists due to geography or failure to receive a referral for follow-up care at initial symptoms.
- Patients may progress to more severe disease states by the time they receive an accurate diagnosis. The rarer the disease, the more challenging the diagnosis.
- Forty-one percent of rare disease patients receive at least one misdiagnosis prior to an accurate diagnosis.
- Rare and ultra-rare patients see an average of 4.2 primary care physicians and 4.8 specialists before receiving an accurate diagnosis.
- Patients make an average of 2.4 out-of-state trips related to their rare disease.
- Rare diseases result in emergency room visits an average of 3.7 times and - are hospitalized an average of 1.7 times - for reasons related to their rare disease prior to diagnosis.
- When a rare disease treatment is administered through complex or innovative procedures or requires a period of post-treatment observation and care, there is almost always a limited set of providers offering the treatment. Better out-of-state, out-of-network, and travel cost accommodations are essential to ensuring that patients can receive the care they need.
- Off-label use of treatments indicated for more common conditions are often required to address disease symptoms and/or progression, especially in extremely rare conditions.
- Approximately 7 percent of rare disease patients reported that they were given a false psychological/psychiatric diagnosis that further impeded and delayed their treatment.¹

Rare cancer patients face similar access challenges, including treatment affordability, limited sets of treatment options, and limited sets of clinicians and facilities with expertise in treating their cancer and navigating payer-related impediments to access.

Individually, these access challenges can present inconveniences, frustration, and delays in receiving care. Cumulatively, they can exert an overwhelming burden on ultra-rare disease and rare cancer patients and their families - delaying access to treatments crucial to avoid further disease progression, disability or, for some conditions, death.

¹ [Rare Diseases: Although Limited, Available Evidence Suggests Medical and Other Costs Can Be Substantial | U.S. GAO](#) (October 18, 2021).

1. Prescription Drug Provisions of the Inflation Reduction Act Increase the Need for CMS Oversight on Medicare Advantage Prescription Drug Plan (MA-PDP) Formulary Structures and Utilization Management Tools

CMS' 2024 final rule² simplified and streamlined utilization management processes for managed care plans in Medicare, Medicaid, and other federal health programs. Unfortunately, that rule did not apply to prior authorization, step therapy, or other utilization management protocols applied to drugs due to CMS' belief that "the processes and standards for prior authorization of drugs differ from the other 'items and services'" and its conclusion that including drugs in the rule would create "operational complexities."

Haystack Project strongly believes that CMS' decision to carve out drugs from the 2024 final rule, combined with the 2025 Part D redesign implementation and 2026 introduction of a negotiated "Fair Market Price" for some prescription drugs creates an acute need for heightened CMS oversight and scrutiny that will require collection of data from Part D plans, including MA-PD plans.

A 2023 double-blind, web-based survey distributed through Cencora's Managed Care Network to pharmacy directors, medical directors, and contracting managers/directors provides insight into how managed care entities perceive and will likely react to the IRA drug provisions³. Of note, most respondents expect that the IRA's Part D changes will lead to narrower formularies in comparison to pre-IRA formulary design. Just 20% of managed care executives expected that there would be little to no change in formulary coverage. In addition, most payers are keenly aware of the increased liability for Part D plans and expect:

- greater use of utilization management tools
 - o 42% anticipated greater utilization management overall.
 - o 32% expect greater utilization management for high-cost medications.
 - o 10% (n = 5) anticipate no change
- Increased Part D plan premiums
 - o 8% anticipate a premium increase greater than 10%.
 - o 40% expect an increase from 5% to 10%.
 - o 18% anticipate an increase up to 5%.
 - o 12% believe Part D plan premiums will remain at their current levels.
 - o No payers expect that premiums will be lower than current levels.

The increased financial liability for Part D plans is not the only factor likely to impact MA-PD plan behaviors. As negotiated drug prices are implemented, plans will face downstream

² Medicare and Medicaid Programs; Patient Protection and Affordable Care Act; Advancing Interoperability and Improving Prior Authorization Processes, 89 F.R. 8758 (Feb. 8, 2024), [2024-00895.pdf \(govinfo.gov\)](#).

³ Ford C, Westrich K, Buelt L, Loo V. Payer reactions to the implementation of the Inflation Reduction Act: forecasting future changes to Medicare Part D plans. Presented at: AMCP Nexus 2023; October 16-October 19, 2023; Orlando.

impacts to their bottom line as the traditional rebates (reflected after the point of sale) are replaced by the MFP (reflecting discounted cost at the point of sale). Manufacturers of drugs subject to an MFP may be unwilling to offer rebates to plans and their Pharmacy Benefit Managers (PBMs). The dynamics are uncertain and will likely vary based on whether there are other available drugs within the same category and class as the selected drug, as well as the PBM's and/or plan's ability to contract with manufacturers for favorable rebates on non-selected drugs.

Although the IRA requires that plans cover all selected drugs, plans can posit a "reasonable justification" for placing drugs subject to an MFP on a non-preferred tier and/or subjecting those drugs to utilization management policies. Absent CMS intervention and/or oversight, it is likely that plans will determine which drug(s) are associated with the lowest financial liability and steer patients toward that drug through formulary inclusion/exclusion and tier placement. If, for example, a drug competing with a selected drug is associated with rebates making it more favorable to a PBM and/or plan sponsor, that drug could be placed on a preferred tier with the selected drug's non-preferred tier placement yielding an increased cost-sharing responsibility for beneficiaries using the selected drug. Similarly, a selected drug might be the only available alternative for beneficiaries despite competing products that may offer improved effectiveness and/or greater tolerability.

Haystack Project urges CMS to prioritize efforts to collect data on plan behavior and any changes impacting beneficiary access to drugs in the coming years as the IRA's Part D redesign and drug price negotiation provisions are implemented.

2. Medicare Advantage (MA) and MA-PD Plan Data Related to Utilization Management Tools

Haystack Project appreciates that CMS seeks input on the types of Medicare Advantage (MA) plan data the Agency should collect to enable insight that might inform future rulemaking. Given the increasing percentage of Medicare beneficiaries electing to enroll in MA plans, it is particularly important that CMS collect sufficient data to enable the level of transparency required to ensure that MA plans operate to deliver high quality care to Medicare beneficiaries without overburdening clinicians.

We were particularly pleased that CMS specifically seeks stakeholder recommendations on data related to beneficiary access to care, including prior authorization and other utilization management strategies. Providers struggling to efficiently and effectively treat their patients spend countless hours wrestling with the myriad requirements, processes and procedures payers implement – hours that would be better spent with patients.

As a threshold matter, Haystack Project believes that utilization management (UM) tools, including prior authorization, step therapy, and any other mechanisms should only be implemented when there is a clear, evidence-based link to improved clinical outcomes.

The proliferation of UM policies throughout the MA program have interfered with shared decision making between the patient and their clinician, overburdened clinician offices, and delayed (or even denied) timely access to necessary medical care. Plans and providers spend countless hours imposing or resolving these processes and plans often pay other entities to adjudicate each prior authorization request or step therapy protocol reconsideration. Ultimately, unless these processes are judiciously implemented to align covered treatments with clinical guidelines and shared decision making between patients and their clinicians, their function will primarily be to delay or even block access to medically necessary care while exacting time and resource burdens on providers. The MA program was intended to improve cost-efficiency and access to quality care, and MA plan UM tools should further, not frustrate, that goal.

Haystack Project appreciates CMS' recent attention to the over-use and misuse of prior authorization processes within the MA program, and urges the Agency to collect data on prior authorization processes from MA plans, including information on:

- Availability and use of electronic prior authorization request mechanisms among providers.
- Resolution of prior authorization requests through a single electronic communication session, including the number of approvals, denials, and requests for information.
- Timely communication of a clear rationale for denying any prior authorization request.
- MA plan systems that are accessible to providers and patients and identify the items and services for which prior authorization is required as well as any documentation requirements.
- Timely communication of prior authorization denials that inform the provider of next steps, including any available appeal.
- Detailed information on MA plan payments to any entity processing prior authorization requests, including the name of the entity receiving payment.
- Prior authorization denials based on dose, frequency, or duration of requested item or service, including any alternative treatment, dose, frequency or duration ultimately approved and provided to the beneficiary.

Haystack Project is similarly concerned CMS has not maintained the oversight required to ensure that any patterns and practices within the MA program that achieve plan savings – and profit accrual – simply by delivering less care than Medicare fee-for-service beneficiaries are able to receive. The MA program was never intended to be an alternative to Medicare coverage; it was designed as an alternative, and ideally more coordinated, care delivery system modeled on managed care policies offered by commercial insurers. Utilization management strategies that, like step therapy protocols, go to the heart of coverage and inject considerations beyond Medicare's "reasonable and necessary" standard, were only recently implemented and should be prohibited. As detailed below,

step therapy protocols are particularly harmful to rare disease and rare cancer patients and, to the extent that they are permitted, should be firmly based on clinical evidence and guidelines and function solely to **improve outcomes** for beneficiaries.

We urge CMS to implement data collection measures to evaluate the extent to which MA plans are denying access to items and services that are covered under Medicare fee-for-service by:

- Requiring that when no applicable Medicare statute, regulation, National Coverage Determinations (NCD), or Local Coverage Determinations (LCD) establishes when an item or service must be covered, MA organizations must cover the service and collect data from plans on:
 - o The evidence from treatment guidelines or scientific literature that justify any coverage denial or imposition of step therapy protocols.
 - o Ensure public availability of scientific rationale for coverage denials, including step therapy protocols.
- Prohibiting MA plans from denying coverage for an item or service that is not subject to noncoverage under Medicare fee-for-service unless the denial is reviewed by a clinician with expertise appropriate for the item/service. MA and MA-PD plans should submit data on:
 - o The disease-specific experts providing consultation (including specialty, diagnoses/treatments on which the expert provided consultation, whether peer-to-peer discussions were conducted, time to resolution, etc.) as well as denials not reviewed by a clinical expert.
- Requiring that MA plans implement a Utilization Management review committee to ensure that its prior authorization, step therapy, and other utilization management tools, including those for drugs, are grounded in science is only impactful in facilitating access and reducing clinician burden if payers rely on these committees as CMS intended. We urge CMS to maintain oversight on plan compliance.
- Developing a mechanism through which patients and clinicians can report on and resolve real world experiences that place significant burdens on access to care.

UM strategies, including unjustified prior authorization and claim denials can threaten continuing viability of rural hospitals.

There is a body of anecdotal evidence that the combination of increased MA plan enrollment, particularly in rural areas, with proliferation of seemingly routine claims denials among MA plans is narrowing the thin financial viability margins for rural hospitals. A 2022 Inspector General report lends credibility to this contention in that it found that the 15 top

Medicare Advantage plans denied authorization for 13 percent of June 2019 prior authorization requests that had met Medicare payment rules. The plans also denied payment for 18 percent of claims qualifying for payment.⁴

One rural hospital executive discussed a two-year study conducted to compare reimbursement from traditional Medicare patients versus what it received from Medicare Advantage plans. He found that the plans paid \$4.5 million less than Medicare fee-for-service – an amount representing total revenue for approximately one month.⁵

While the financial consequences for rural providers may not require different sets of data collection and CMS oversight, they do illustrate the breadth and magnitude of the problem **all** providers treating MA beneficiaries face.

Rare and ultra-rare disease patients face unique challenges when UM policies are applied to their treatment(s).

Haystack member organizations have continued to relate their experiences navigating prior authorization processes and utilization management tools. The most frequently encountered challenges leading to treatment delays include:

Step therapy protocols. Step therapy is a well-known, frequently encountered utilization management strategy. Requiring patients to “step” through older, less costly treatments before allowing access to newer, often more innovative or targeted options may be less of a problem in disease states for which several treatments are available. Individuals with extremely rare conditions seldom have any on-label treatment much less more than one FDA-approved treatment available, and any off-label uses of existing drugs are rarely found in the various compendia and other sources plans commonly rely on to determine coverage. This means that even if plans rely on clinical evidence in developing step therapy protocols, they are not considering patients with rare and ultra-rare conditions. Haystack Project strongly believes that given that Medicare’s beneficiary population includes a disproportionate share of patients with multiple chronic conditions, comorbidities, and other patient-specific factors, denying access to a prescribed treatment based on step therapy protocols is not only inappropriate, but potentially dangerous. Within the context of off-label use in rare conditions, it is even more so as there is a greater likelihood that this UM tool will require failure on a treatment that is not useful in a rare or ultra-rare disease and/or that may be harmful to the patient.

Haystack does not expect that plans would maintain up-to-date clinical information on every treatment for every rare disease. We do, however, urge CMS to collect data from MA

⁴ [OEI-09-18-00260.pdf \(hhs.gov\)](#)

⁵ [By repeatedly denying claims, Medicare Advantage plans threaten rural hospitals and patients, say CEOs \(nbcnews.com\)](#)

and MA-PD plans on whether an expedited review process and emergency doses are available and utilized for rare disease patients when UM mechanisms are applied to their prescribed treatment.

NDC “blocks” and “lockouts.” It is relatively common for plans to systematically block coverage of newly approved drugs and biologicals for 6-12 months or longer under the rationale that formulary inclusion requires review of the plan’s pharmacy and therapeutics committee. These blocks apply to patients newly seeking treatment as well as to those who have benefited from the treatment through clinical trial participation, open label extensions, and expanded access programs. Haystack recognizes that the mechanism has utility and may be a reasonable approach in more common conditions. Access delays for new drugs offering incremental benefits in efficacy, safety, or convenience over existing treatments may be frustrating, but they are generally not harmful to the patient.

In rare conditions declining access to what may be the only on-label treatment is an example of the types of unintended consequences rare disease patients face throughout their health care journey and illustrates how applying policies with seeming equality drives real world inequities that can harm patients. An expedited formulary review process applicable to newly approved treatments for rare diseases would mitigate the disparate impact that blocks and lockouts exact on rare and ultra-rare patients.

We urge CMS to collect and examine data on the time between market entry of a new treatment and the date MA and MA-PD plans enable access, as well as any UM policies applied to the treatment and/or formulary exception, reconsiderations or appeals processes required for beneficiary access.

Access to off-label uses. Individuals relying on Medicare Part D often find that the off-label treatments used within the standard-of-care are not included in the set of compendia that define what is and is not a “Part D covered drug.” The rarer the disease, the less likely it is that medically accepted treatments will be published in compendia. Patient access programs are not generally available since a manufacturer offering free or discounted drug in this patient population would face off-label promotion scrutiny and potential liability.

Haystack Project urges CMS to collect⁶ data from MA and MA-PD plans on coverage denials for prescribed off-label treatments for rare disease uses not included in CMS-approved compendia, including what, if any, treatment was offered and provided to the patient, the time period from initial coverage denial to final resolution, and any reconsideration and/or appeals processes initiated by the beneficiary or their provider.

⁶ [NCCN Guidelines Update: Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma in: Journal of the National Comprehensive Cancer Network Volume 21 Issue 5.5 \(2023\) \(jnccn.org\)](https://www.jco.org/journal/41/21/21000)

The IRA drug negotiation program could have an additional impact on rare cancer patients.

For the initial year of the Medicare Drug Price Negotiation Program (MDPNP), Imbruvica® was the only cancer treatment selected for negotiation. Imbruvica® is a Bruton's tyrosine kinase (BTK) inhibitor that initially received accelerated approval in 2013 for the treatment of mantle cell lymphoma (MCL, voluntarily withdrawn in 2023) in patients who had received at least one prior therapy. It was subsequently approved for chronic lymphocytic leukemia (CLL) and small lymphocytic lymphoma (SLL) with 17p deletion, Waldenström's macroglobulinemia (WM), (a rare form of non-Hodgkin lymphoma), marginal zone lymphoma (MZL, voluntarily withdrawn in 2023), and chronic graft versus host disease (cGVHD) after failure of one or more treatments. The indication with the highest impact to the Medicare program is chronic lymphocytic leukemia (CLL), which is a chronic blood cancer of a type of white blood cell called the B-lymphocyte. CLL is the most common leukemia in adults in the United States, and is also classified as a type of non-Hodgkin's Lymphoma (NHL).

CLL is extremely heterogeneous, meaning each person's disease course and progression can be extremely variable. Some experience rapid deterioration due to having an aggressive form of the disease and survive for as little as two years, while other have a less aggressive form of the disease, never need treatment, and can expect to have a normal life expectancy.

Although most CLL/SLL patients can expect a response to initial therapy, nearly all current treatment options are palliative and not curative. Most patients will experience one or more relapses throughout the course of their disease, and many patients must either change treatments, take a "drug holiday," or adjust dosing due to drug intolerance. For patients with relapsed or refractory disease (or treatment intolerance), treatment decisions are highly individualized based on prior therapies, prior response, the reason for discontinuation of previous therapy, comorbidities, biomarker characteristics, patient preference, and therapeutic goals. Patients can experience serial relapses and may be treated with all available agents at some point during their disease course.

Zanubrutinib is a newer BTK inhibitor that has demonstrated fewer cases of atrial fibrillation than Imbruvica and no cardiac-related deaths. Patients taking zanubrutinib also have a higher response rate and a longer time to disease progression. The reduced side effect profile for zanubrutinib will enable patients to remain on treatment longer, but once their disease progresses, they cannot simply switch to one of the other irreversibly binding BTK inhibitors that are approved for CLL and expect a response. This is because once a drug within that same BTK inhibitor drug class has failed the patient, all drugs within that same class will also likely fail.

According to NCCN Guidelines, the most appropriate frontline treatment for CLL and SLL depends on patient-specific factors, including characteristics of the cancer and mutation

status, age, and comorbidities. Subsequent lines of therapy are chosen based on the previous treatment as well as the factors outlined above. BTK inhibitors offer considerable improvements in care for patients but can result in drug intolerance requiring interruption, dose reduction, and even treatment discontinuation. Although clinical guidelines and recommendations recognize that newer BTK inhibitors have greater tolerability that would tend to improve outcomes, there is still much to learn about the various BTK inhibitors through real world data generated over time. BTK inhibitors are also increasingly being studied in combination with other treatment options, and these uses should also be covered by MA and MA-PD plans when the patient and their clinician determine that it is the best treatment option.

For patients, it is vital that payers, including MA and MA-PD plans, include all available treatment options in their formularies, without imposing step therapy protocols, so that clinicians and patients are able to make treatment decisions based on what will enable the patient to achieve a durable treatment response while maintaining their quality of life. There is substantial concern that if Imbruvica® is priced in a way that encourages health plans to insist on it as a first step, more patients will be forced to experience potentially dangerous serious adverse events and discontinue treatment. At the same time, patients need to have access to all viable treatment options and those using Imbruvica® successfully for their cancer are unable to take an alternative BTK inhibitor that may be more financially advantageous to a plan due to rebates and other price concessions.

We urge CMS to collect data on MA-PD formulary inclusion and placement for all BTK inhibitors, any changes in tier placement and/or beneficiary cost sharing, as well as the contours and evidentiary basis of any UM policies applied to one or more products within the BTK inhibitor class.

CMS should collect data needed to enforce beneficiary access to drugs within “protected classes.”

Haystack Project has long been concerned that the protections that have been codified since 2006 for Part D drugs within the six “protected” classes, i.e., immune-suppressants, antidepressants, antipsychotics, anticonvulsants, antiretrovirals, and antineoplastics, have eroded from one year to the next. Individuals with extremely rare conditions, including those with rare forms of epilepsy, often require approaches to treatment that differ from treatment of more common forms of the condition. This could mean that a specific anticonvulsant drug is required, that two or more treatments are needed, or even that drug combinations that include products outside the anticonvulsant class are used to control seizures. Rare, genetic conditions impacting the immune system similarly require distinct, disease-specific treatment regimens to reduce disease burden or extend life.

CMS’ determination that the nature of these classes of drugs and the condition(s) they treat justify a requirement that plans include all or substantially all drugs within the class was designed to ensure that formulary designs do not disadvantage and discriminate against

the vulnerable patients requiring access to specific drugs or combinations of drugs. We urge CMS to collect data on any formulary and/or UM mechanisms applied to these classes and enforce this important regulatory beneficiary protection.

3. Network Adequacy

Haystack Project understands that CMS currently collects extensive data from Medicare Advantage (MA) plans on provider networks, particularly in rural and underserved urban areas. We urge the Agency to optimize the impact of this data on ensuring equitable access to care through detailed analyses that focus on Medicare's particularly vulnerable rare disease and rare cancer patient populations. Ideally, these analyses should examine changes in beneficiary access, patient satisfaction, and health outcomes, and enable CMS to not only assess beneficiary needs but identify gaps in access to care attributable to provider network factors.

For rare and ultra-rare disease patients, the greatest challenge is simply finding a provider with the expertise to diagnose and treat their condition. There is a shared understanding within the stakeholder community that patients, including those with rare and ultra-rare conditions, would benefit from a reliable, one-stop source of information to identify in-network specialists with disease-specific expertise. The American Medical Association (AMA) for example, recently voted to adopt a policy urging Medicare Advantage plans to maintain accurate provider directories. AMA board member Scott Ferguson, MD noted that "[p]atients face a false appearance of choice when Medicare Advantage plans create networks that are too thin and directories that are too flawed. A comprehensive and authoritative source of accurate information is needed from federal authorities to support patients in Medicare Advantage."

Haystack Project urges CMS to ensure that MA enrollees with rare and ultra-rare conditions have access to specialties with experience and expertise in addressing their specific condition. We understand that it would be extremely difficult for plans to map every rare and ultra-rare condition to a particular set of specialists as they develop their provider network. A more pragmatic and workable approach would be to require that MA plans maintain an expedited process through which their rare and ultra-rare disease enrollees could, upon recommendation from their treating provider, access an out-of-network clinician or facility at in-network cost-sharing levels.

We similarly urge CMS to evaluate beneficiary access to MA provider directories, both before enrolling in an MA plan and throughout their enrollment. This evaluation should also examine the accuracy of directories, including whether each provider listed is accepting new MA patients, any referral or other processes required to access each provider the set of hospitals for which the clinicians have privileges, average wait time to secure an appointment as a new patient, and any available processes to secure a visit on an urgent basis.

We similarly urge CMS to require data from MA plans on requests for out-of-network care, including the MA plan’s action, the care requested, the diagnosis, the timeline for a decision and access to care, and the reason for any request denials.

Telemedicine and other care delivery flexibilities can enhance provider capacity, but MA plan network adequacy requirements should reflect access to in-person care.

Haystack Project and its member organizations found that telemedicine and the “flexibilities” implemented during the Covid-19 public health emergency offered an opportunity for patients and providers to explore new and potentially improved ways of receiving care. The Medicare Payment Advisory Commission (MedPAC) has conducted analyses on the impact that telehealth services can have on health care utilization and outcomes and suggested that CMS monitor and evaluate telehealth effectiveness. We urge CMS to accept this MedPAC recommendation on data collection.

We have also heard from patients and caregivers regarding the barriers individuals with hearing and/or visual impairments face in seeking virtual care. Usher Syndrome, for example, is an exceedingly rare (approximately 25,000 US patients), inherited disease causing combined hearing loss and vision loss from retinitis pigmentosa. For these patients, it is essential that remote care includes access to an ASL interpreter if they have sufficient remaining vision, or a tactile sign interpreter if they do not.

We urge CMS to collect data to evaluate the extent to which MA plans have the capabilities and capacity to address the needs of these patients that would otherwise impede access to telemedicine services.

For rare cancer patients, access to an adequate network requires inclusion of one or more NCI Comprehensive Cancer Centers.

One of the drawbacks of MA plans is that they frequently rely on relatively narrow provider networks that, for cancer patients, means that their care will be received through community hospitals and oncology practices. This may not impact outcomes for patients with cancers requiring straightforward, well-established treatment protocols. The same cannot be said for patients with rare or refractory cancers or conditions for which emerging therapies such as genomic-based precision medicine and CAR-T immunotherapies are available.

Medicare fee-for-service beneficiaries can access any of the 56-NCI-designated Comprehensive Cancer Centers, provided they are willing and able to travel to the center. Unfortunately, most MA plans – 60 percent – do not include even one of these centers, closing off MA beneficiary access to facilities offering advances in diagnostics and treatment, including access to clinical trials. MA patients have approximately one-fifth the chance of receiving care from an NCI-designated center as their fee-for-service counterparts, and about one-third the chance of receiving care at a teaching hospital.

This disparity in access to a broad network of providers has created significant disparities for MA patients, including:

- Higher mortality rates for complex procedures⁷
 - o Twice as likely to die within a month of pancreatic surgery.
 - o Fifty percent more likely to die within a month of stomach and liver cancer surgery.
- Inability to access CAR-T cell therapies that have increased success rates in treating some leukemias and lymphomas by 50-80 percent.⁸
- Inability to participate in a clinical trial due to lack of academic medical centers in the provider network.

We urge CMS to require MA plan inclusion of one or more NCI-designated centers and one or more academic medical centers in each plan network. At a minimum, we strongly urge CMS to apply heightened scrutiny, including enhanced data requests, to MA plans failing to enable meaningful access to these facilities for their cancer patients.

Conclusion

Haystack Project and its member organizations appreciate the opportunity to respond to CMS' Request for Information on Medicare Advantage Plan Data. If you have any questions or would like to discuss the issues raised in our comments, please contact our policy consultant, M Kay Scanlan, JD at (410) 504-2324.

Alliance to Cure Cavernous Malformation

Alpha-1 Foundation

ALS Association

Association of Cancer Care Centers (ACCC)

Biomarker Collaborative

Born a Hero, Research Foundation

CancerCare

Casey's Cure

CDG Care

Chondrosarcoma Foundation

⁷ [Mustafa Raoof et al.](#) Medicare Advantage: A Disadvantage for Complex Cancer Surgery Patients. *JCO* **41**, 1239-1249(2023).DOI:[10.1200/JCO.21.01359](https://doi.org/10.1200/JCO.21.01359)

⁸ See, e.g., <https://www.shebaonline.org/car-t-cell-therapy-success-rate-in-israel/>

CLL Society
CSNK2A Foundation
Cure GABA-A
Cure VCP Disease
Cutaneous Lymphoma Foundation
Desmoid Tumor Research Foundation
Dup15q Alliance
Exon 20 Group
FACES: The National Craniofacial Association
Galactosemia Foundation
ICAN, International Cancer Advocacy Network
International Fibrodysplasia Ossificans Progressiva (FOP) Association
Luka Shai Foundation
MET Crusaders
MLD Foundation
No Stomach for Cancer
NTM Info & Research
NW Rare Disease Coalition
Ovarian Cancer Research Alliance (OCRA)
PD-L1 Amplifieds
Sudden Arrhythmia Death Syndromes (SADS) Foundation
SYNGAP1 Foundation
The Healing NET Foundation
The International Waldenstrom's Macroglobulinemia Foundation (IWMF)
Triage Cancer
TSC Alliance
United Porphyrias Association
Usher 1F Collaborative
Usher Syndrome Coalition