CLL SOCIETY

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January 27, 2025

Jeff Wu
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-4208-P
7500 Security Boulevard
Baltimore, MD 21244–1850

RE: CMS-4208-P; Medicare and Medicaid Programs: Contract Year 2026 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly

Dear Acting Administrator Wu:

CLL Society appreciates the opportunity to submit its comments on the Centers for Medicare & Medicaid Services' (CMS') Proposed Rule setting forth policy and technical changes to Medicare Advantage (MA), Part D, the Medicare Cost Plan Program, and the Programs of All-Inclusive Care for the Elderly (PACE). We look forward to working with the Trump Administration as it strives to deliver on its promises to improve the health and lives of America's elderly and disabled citizens.

CLL Society is dedicated to addressing the unmet needs of the chronic lymphocytic leukemia and small lymphocytic lymphoma (collectively referred to as CLL) community through patient education, advocacy, support, and research. We are the largest nonprofit focused exclusively on the unmet needs of patients living with CLL.

We strive to fulfill our primary mission of ensuring that patients have access to safe and effective treatment options by informing patients and caregivers about the rapidly changing therapeutic landscape and the importance of clinical trials, supporting and building patient networks, engaging in research, and educating providers and patients. As an organization, we also recognize that the healthcare landscape extends beyond science, clinical care, and patient support.
The Medicare program is critical for our patients given that the average age for individuals newly diagnosed with CLL is 65-70 years. As increasing numbers of beneficiaries choose to enroll in Medicare Advantage, we have renewed our focus on ensuring that MA policies enable access to needed treatments without unduly burdening clinicians. This is particularly important as

implementation of the Inflation Reduction Act will continue to shift incentives for MA and Part D plans to push clinicians away from prescribing some treatments in favor of others.

Our comments provide a brief background on CLL to illustrate the importance of ensuring that patients have access to all treatment options, identify provisions within the Proposed Rule likely to help or hurt CLL patients, and make recommendations to CMS as it finalizes refinements to the MA and Part D programs for the 2026 contract year.

Background

CLL is a chronic blood cancer of a type of white blood cell called the B-lymphocyte. In CLL there is a progressive accumulation of too many mature B-lymphocytes. CLL is the most common leukemia in adults in the United States, with around 21,000 cases diagnosed annually. It is classified as both a type of leukemia and a type of non-Hodgkin's Lymphoma (NHL). SLL is simply a different manifestation of the same disease and is best understood as a different stage of CLL where there are not a significant number of cancer cells yet located in the bloodstream.

CLL is extremely heterogeneous, meaning each person's disease course and progression can be extremely variable. Some individuals have an aggressive form of disease, experience rapid deterioration, and may not survive beyond two years. Individuals with a less aggressive form of CLL may never need treatment and can expect to have a normal life expectancy. It is common for clinicians to recommend that newly diagnosed CLL patients be actively monitored without treatment until CLL symptoms emerge.

Targeted therapies such as BTK inhibitors and the BCL2 inhibitor known as venetoclax offer substantial efficacy against CLL/SLL and have transformed care for our patient community. Patients now have more treatment options compared to just years ago when the standard of care was chemoimmunotherapy. Although most CLL patients can expect a response to their initial therapy, most will experience one or more relapses during the course of their disease. In addition to treatment changes due to relapse, many patients are forced to change treatments, take a "drug holiday," or adjust dosing due to drug intolerance. Patients with relapsed or refractory disease (or treatment intolerance) require individualized treatment plans based on prior therapies, prior response, the reason for discontinuation of previous therapy, comorbidities, biomarker characteristics, patient preference, and therapeutic goals.

The unfortunate reality for our patients is that CLL remains incurable despite considerable progress in treatments. The set of treatment options for CLL are not interchangeable alternatives for individual patients as they move through treatment, complete response, relapse, and progression. Patients progressing after both BTK and BCL2 inhibitors face a poor prognosis with few treatment options. Since NCI recommends participation in clinical trials for these patients, it is crucial that MA provider networks enable access to NCA-designated cancer centers and teaching hospitals.

1. **CMS' Implementation of the IRA's Prescription Drug Provisions Must Include Increased Oversight on MA and Part D Formulary Structures and Utilization Management Tools.**

As you are aware, CMS' implementation of the IRA introduces substantial changes to the set of incentives MA and Part D plans have relied upon to maintain financial viability and/or increase profit margins. We have previously expressed our expectation that the drug price negotiation program will have little to no impact on CLL patient costs and urged CMS to ensure that Medicare program savings on negotiated drugs are not achieved at a cost to patients in the form of reduced access to the full set of CLL treatment options.

Unlike the drug price negotiation program, the IRA's redesign of the Part D benefit brings significant financial relief to CLL Society's community of patients and caregivers in the form of a cap on out-of-pocket costs ($2,100 for 2025). This financial relief for patients is, however, associated with a shift in financial responsibility to manufacturers and Part D plans. Elimination of the manufacturer coverage gap discount program, and implementation of a new Manufacturer Discount Program means that for most branded Part D drugs, manufacturers will provide a 10% discount through the initial coverage phase and a 20% discount during the catastrophic phase. There is, however, an exception for "specified small manufacturers" that permits manufacturers to phase-in these discounts over the time period from 2025 to 2031. This phase-in shifts a greater share of costs for these Part D drugs onto Part D plans.

CLL patients and their clinicians are in a uniquely vulnerable position as these statutory changes are implemented as (1) Medicare is the primary payer for a majority of CLL patients; (2) the first-line treatments for CLL (BTK inhibitors) are within the Part D benefit; (3) the BTK inhibitor ibrutinib was the only cancer treatment included in the first round of drug price negotiations; and (4) Zanubrutinib, another BTK inhibitor, will be associated with the phased-in discounts that shift a greater share of financial liability onto Part D plans.

CMS has previously acknowledged that Part D plans would view drugs with negotiated prices less favorably due to the statutory requirement for formulary inclusion undercutting the rebate system that has historically driven formulary coverage. The Agency has stated that it will identify inappropriate formulary listings for these drugs within its formulary review process. This same potential for unfavorable tiering, burdensome prior authorization processes, and inappropriate step therapy protocols exists for non-selected drugs with phased-in manufacturer discount obligations. Specifically, we are concerned that Zanubrutinib (and

other small manufacturer products) might be excluded from plan formularies or limited to use in patients already receiving them or exhibiting intolerance to other BTK inhibitors.

Zanubrutinib is a newer BTK inhibitor that has demonstrated fewer cases of atrial fibrillation than ibrutinib 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.

Last Fall, we met with CMS staff to share information we have received concerning Part D plans and Prescription Benefit Managers (PBMs) that appeared inclined to view small manufacturer drugs unfavorably due to increased plan share of their cost. This presents significant risk to our patients.

NCCN Guidelines for CLL emphasize that the most appropriate treatment plan for a particular patient depends on multiple factors, including the patient's *IGHV* status, del(17p)/*TP53* mutation status, age, and comorbidities.[1] Decisions on subsequent treatment courses are based on the prior therapy received, patient comorbidities, resistant mutations, and other factors. Since CLL is indolent and generally not "curable," our treatment goals are to improve quality of life and prolong overall survival. Patients need access to all BTK inhibitors to avoid (or at least delay) the poor prognosis that will confront them if their disease progresses after exhausting all available treatment options.

The patients, caregivers, and clinicians within CLL Society's community remain hopeful that CMS will implement sufficient formulary and utilization management guardrails to eliminate financially driven treatment plans in favor of clinician judgment and shared decision making. In its Proposed Rule, CMS asked for stakeholder feedback on "whether further programmatic actions within CMS's current statutory authority are necessary to prevent Part D formularies from excluding or disfavoring coverage of generics, biosimilars, and other lower cost drugs."[2] CMS' statutory authority is not limited to cost reduction, and we urge the Agency prioritize

[1] 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)
[2] Regulations.gov

beneficiary access to life-saving cancer treatments with, if not above, Medicare cost savings. Specifically, we urge CMS to:

- Use targeted/enhanced formulary review mechanisms to fully enforce the formulary requirements for drugs within the "protected classes" that CMS identified as "categories and classes of clinical concern" (anticonvulsants, antidepressants, antineoplastics, antipsychotics, antiretrovirals, and immunosuppressants).
    - CMS determined 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. This was intended to ensure that formulary designs do not disadvantage and "discriminate against" the vulnerable patients requiring access to specific drugs or combinations of drugs.

- Reject MA or Part D plan use of utilization management strategies for cancer treatments that do not align fully with NCCN guidelines or push treatment decisions toward or away from specific products used to treat CLL and other cancers.

The bottom line is that there is substantial uncertainty on the extent to which MA and Part D plans will change their business practices in the wake of IRA implementation. A 2023 double-blind, web-based survey[3] distributed through Cencora's Managed Care Network to pharmacy directors, medical directors, and contracting managers/directors provided insight into how they perceive and might respond to the IRA drug provisions. Most respondents anticipate narrower formularies in comparison to pre-IRA formulary design and are keenly aware of the increased liability for Part D plans. Respondents expected:

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

[3] 2024 April JMCP Poster Abstract Supplement - FINAL.pdf

- No payers expect that premiums will be lower than current levels.

CLL Society is concerned that our patients will encounter MA and Part D plans that impose increasing costs while constricting access to care. We urge CMS to monitor the extent to which MA and Part D plans narrow their formularies or impose new utilization management strategies on necessary treatments.

2. Network Adequacy

In its June 2020 Final Rule, CMS indicated in preamble that it would perform network adequacy reviews at the contract level rather than at the plan level. In its Proposed Rule, the Agency indicated that it would consider using plan level data in its network adequacy reviews. We urge CMS to adopt the proposed approach as it will provide a more accurate picture of what Medicare beneficiaries experience, particularly as they seek care for life threatening conditions like CLL. In addition, we strongly urge CMS to consider creating a new facility-specialty type "NCI-designated Cancer Center" under 42 CFR § 422.116.

One characteristic that MA plans tend to share is that they frequently rely on narrow provider networks that, for cancer patients, often means that care is received through community hospitals and oncology practices. This may not impact outcomes for patients with cancers requiring straightforward, well-established treatment protocols. Unfortunately, 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 57-NCI-designated Cancer Centers, provided they are willing and able to travel to the center. Unfortunately, 60 percent of MA plans do not enable access to even one of these centers. The impact on patients is very real and can be profound as they are denied 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 real-world disparity in access has translated into real-world disparities in outcomes for MA patients, including:

- Higher mortality rates for some complex procedures[4]
    - Twice as likely to die within a month of pancreatic surgery.
    - 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.[5]
- Inability to participate in a clinical trial due to lack of academic medical centers in the provider network.

We strongly urge CMS to ensure that MA is a viable coverage choice for Medicare beneficiaries with CLL or other cancers by requiring that plans include (either through in-person access or sufficient telemedicine services to enable treatment planning and consultation) one or more NCI-designated cancer centers and one or more academic medical centers in each ***plan*** network.

Conclusion

CLL Society appreciates the opportunity to contribute the CLL patient perspective as CMS refines its policies for MA and Part D plans. We hope to foster a continuing dialogue and welcome the opportunity to discuss our comments or the experience of CLLL patients generally.

If you have any questions, please feel free to contact me or Saira Sultan, CLL Society's Healthcare Advocacy & Policy Consultant, via email at saira.sultan@connect4strategies.com.

Sincerely,

Carly Harrington
Executive Director, CLL Society

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

[5] See, e.g., https://www.shebaonline.org/car-t-cell-therapy-success-rate-in-israel/