



BY ELECTRONIC DELIVERY

September 6, 2022

Chiquita Brooks-LaSure, Administrator  
Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
7500 Security Blvd  
Baltimore, MD 21244

**RE: CMS-1770-P -- Medicare and Medicaid Programs; CY 2023 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Medicare and Medicaid Provider Enrollment Policies, Including for Skilled Nursing Facilities; Conditions of Payment for Suppliers of Durable Medicaid Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS); and Implementing Requirements for Manufacturers of Certain Single-Dose Container or Single-Use Package Drugs To Provide Refunds With Respect to Discarded Amounts**

Dear Administrator Brooks-LaSure:

We appreciate the opportunity to submit comments on the Centers for Medicare & Medicaid Service (CMS) proposed rule updating and refining Medicare payment policies under the Physician Fee Schedule (PFS).

CLL Society is a non-profit, patient advocacy organization focused on patient education, support, advocacy, and research. We are dedicated to addressing the unmet needs of those living with chronic lymphocytic leukemia (CLL), small lymphocytic lymphoma (SLL), and those who care for them. CLL Society is the largest patient-centric nonprofit organization focused exclusively on the nearly 200,000 Americans living with CLL/SLL (SEER database, January 2018). We operate under the guidance of a Medical Advisory Board and Expert Medical Council, which are comprised of world-class experts in CLL/SLL research and patient care. Our interest is in ensuring that patients have access to safe and efficacious treatment options.

Chronic lymphocytic leukemia is the most common leukemia in adults. It is a type of cancer that starts in the cells that become the white blood cells called lymphocytes located within the bone marrow. While the cancer begins growing in the bone marrow, it then eventually is found in the blood. Importantly, people with CLL/SLL are considered moderately to severely immunocompromised regardless of their treatment status and are more vulnerable to infections because they have a cancer of the immune system.



## COVID-19 Provisions

In this year's proposed rule, CMS indicates that it will generally continue its COVID-19 related policies until the end of the calendar year in which the emergency use authorization (EUA) declaration for drugs and biologicals under section 564 of the Food, Drug, and Cosmetic Act (FDCA) terminates, instead of the end of the calendar year in which the public health emergency (PHE) ends. CLL Society is particularly concerned with coverage and payment for COVID-19 pre-exposure prophylaxis (PrEP) preventative therapies (such as Evusheld).

CLL Society strongly supports CMS's proposal to continue the existing policy to pay for Evusheld (tixagevimab co-packaged with cilgavimab), a monoclonal antibody (mAb) that received Emergency Use Authorization from the FDA for prevention of COVID-19. Despite receiving all recommended COVID-19 vaccine doses, those with CLL/SLL typically do not have a robust COVID-19 antibody response leaving them extremely vulnerable without additional protective measures. All those with CLL/SLL are moderately to severely immunocompromised<sup>1</sup> which the NIH has noted.<sup>2</sup> According to the CDC, those who are moderately or severely immunocompromised may need Evusheld.<sup>3</sup>

Patients with CLL/SLL are much less likely to be protected by vaccinations<sup>4</sup> and are at much higher risk for poor outcomes with COVID-19, including death. This is regardless of their vaccination status, antibody levels, treatment status, and no matter what the prevalent circulating SARS-CoV-2 variant is at the time.<sup>5</sup>

*Therefore, we strongly support CMS's proposal to continue the existing policy to pay for monoclonal antibodies such as Evusheld for use as pre-exposure prophylaxis prevention of COVID-19 and their administration under the Part B vaccine benefit, even after the product(s) receives FDA approval and the EUA declaration for such products are terminated.* This policy will help support the provision of monoclonal antibodies to patients with CLL/SLL, as well as others who are moderately to severely immunocompromised.

Once again, CLL Society appreciates the opportunity to comment on the CMS Proposed Rule, and we look forward to future discussions on how to address the healthcare needs of patients living with CLL and SLL.

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<sup>1</sup> Can Immunocompetence Be Restored in Chronic Lymphocytic Leukemia? *Hematol Oncol Clin N Am* - (2021) — <https://doi.org/10.1016/j.hoc.2021.03.010>

<sup>2</sup> <https://www.covid19treatmentguidelines.nih.gov/special-populations/immunocompromised/>

<sup>3</sup> <https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medical-conditions.html>

<sup>4</sup> Antibody Response to COVID-19 Vaccination in Adults with Hematologic Malignant Disease Published Online: August 11, 2021. doi:10.1001/jamaoncol.2021.4381

<sup>5</sup> Patients with CLL have similar high risk of death upon the omicron variant of COVID-19 as previously during the pandemic (preprint) <https://www.medrxiv.org/content/10.1101/2022.03.01.22271685v1>



CLL SOCIETY

Thank you for your consideration of these comments.

Sincerely,

Brian Koffman, MDCM (retired), MS Ed  
Co-Founder, Executive Vice President, and Chief Medical Officer  
CLL Society, Inc.