



January 7, 2022

Dana Hittle
Interim Deputy State Medicaid Director
500 Summer St. NE, E65
Salem, OR 97301

RE: Comments on the Oregon 1115 Demonstration Waiver for the Oregon Health Program.

Dear Deputy Director Hittle:

At The Leukemia & Lymphoma Society (LLS), our mission is to cure leukemia, lymphoma, Hodgkin's disease and myeloma, and to improve the quality of life of patients and their families. We support that mission by advocating that blood cancer patients have sustainable access to quality, affordable, coordinated healthcare. On behalf of the thousands of Oregonians whose lives have been changed forever by blood cancer, we appreciate this opportunity to comment on the Oregon 1115 Demonstration Waiver for the Oregon Health Program.

LLS supports the focus that the Oregon Health Program has placed on equitable access to healthcare in the 1115 Demonstration Waiver and thanks the department for its innovative thinking and leadership to eliminate inequities in access to care. In addition, Oregon's request to provide multi-year continuous enrollment for children under six and continuous eligibility for all beneficiaries ages six and over will help to eliminate gaps in coverage.

Unfortunately, this waiver contains multiple proposals that undermine access to care for patients with blood cancer. LLS is concerned the proposed closed formulary for adult beneficiaries will make it harder for patients to access the medications they need to stay healthy. We also oppose Oregon's proposals to limit retroactive coverage for nearly all Medicaid beneficiaries and to waive the Early and Periodic Screening, Diagnostic and Treatment (EPSDT) benefit for beneficiaries over the age of one, as both proposals will significantly jeopardize access to care for patients we represent.

LLS offers the following comments and suggested changes on the 1115 Demonstration Waiver for the Oregon Health Program.

Continuous Eligibility

LLS supports the request for continuous enrollment for children under six and two-year continuous eligibility for beneficiaries over the age of six. Continuous eligibility reduces gaps in coverage that prevent patients from accessing the care that they need. Continuous eligibility increases equitable access to care, as studies show that children of color are more likely to be affected by gaps in coverage.ⁱ Research has also shown that individuals with disruptions in coverage during a year are

more likely to delay care, receive less preventive care, refill prescriptions less often, and have more emergency department visits.ⁱⁱ People in the midst of cancer treatment, for example, rely on regular visits with healthcare providers, and many of those patients must adhere to frequent, if not daily, medication regimens. The loss of coverage or a gap in coverage is a grave prospect for anyone living with blood cancer. Continuous eligibility will help reduce these negative health outcomes.

Closed Formulary

LLS is concerned that the proposal to adopt a commercial-style closed formulary and to exclude from that formulary drugs with “limited or inadequate evidence of clinical efficacy” will reduce access for certain cancer patients to the only appropriate treatment available. This proposal may negatively impact access to care for patients living with a range of serious diseases and conditions. But for patients living with cancer, this proposal is especially grave, as there is very little interchangeability among the drug therapies used to treat most cancers, including most blood cancers. Typically, treating cancer is a profoundly complex undertaking. Indeed, even among patients with the same diagnosis, the same treatment may be insufficient or altogether inappropriate.

In particular, LLS is alarmed by the language on page 31 of the Application for Renewal and Amendment stating that “[m]any drugs coming to market through the FDA’s accelerated approval pathway have not yet demonstrated clinical benefit and have been studied in clinical trials using only surrogate endpoints” and by Oregon seeking “the ability to use its own rigorous review process to determine coverage of new drugs and to prioritize patient access to clinically proven, effective drugs.”

In our own analysis of drugs with an FDA-approved blood cancer indication approved prior to July 2021, more than 40 were approved through accelerated pathways, including 31 just in the past decade. Furthermore, the State’s claim that this will induce programmatic savings is diminished by the intent to “use its own rigorous review process” to determine a drug’s efficacy. LLS is alarmed by the prospect of a secondary state-level review process that claims rigor without any transparency around the methods or standards the state intends to put in place to achieve it. Indeed, the application provides no detail on how Oregon will establish such a review process. Given the rigorous standards the FDA and manufacturers follow before a drug reaches the market through even an accelerated pathway, such a program is likely to be expensive: to Oregon’s Medicaid budget, to those beneficiaries who may be denied access to a treatment or therapy while the State decides whether they think it merits coverage, and potentially even to the broader healthcare system if such a secondary review process results in health spending that would have been obviated by timely adherence to the FDA-approved medication. If adopted in multiple states, this could result in dramatic variation in access to new cancer therapies across the country.

In its application, the State suggests that they seek the same “discretion” regarding formulary design as that available to commercial payers. Enrollees in commercial plans, however, have access to appeals and exception processes that can provide access when necessary to excluded drugs, whereas the Oregon application includes no indication of intent to provide that same due process to Medicaid beneficiaries impacted by a formulary limitation. To make adequate comparisons between Medicaid

and commercial payer formularies, it is also important to note that commercial payers do not receive the same mandatory rebates that Medicaid programs, including Oregon's, receive for all drugs covered under the program. Moreover, patients covered by commercial plans can choose alternative coverage, while Oregonians on Medicaid have no similar alternative.

Given the small population of cancer patients relying on these new medications and the importance of timely adherence to treatment regimens, LLS believes the creation of a closed formulary, without a clear and robust exception process, would be harmful to blood cancer patients.

While LLS certainly appreciates the need for state resources to be spent on benefits and services of high value, adopting this as a blanket approach will no doubt prevent or delay some cancer patients from accessing medically appropriate and potentially life-saving therapies simply because they are Medicaid beneficiaries. LLS requests that the Oregon Health Program remove these requests and provide a robust, open formulary for all beneficiaries that will allow patients to access the medications that their providers believe are best for them.

Retroactive Coverage

LLS is concerned by the proposal to continue to eliminate retroactive coverage for nearly all beneficiaries, excluding the aged, blind and disabled. Retroactive eligibility in Medicaid prevents gaps in coverage by covering individuals for a set amount of time prior to the month of application, assuming the individual is eligible for Medicaid coverage during that time frame. It is common that individuals are unaware they are eligible for Medicaid until a medical event or diagnosis occurs. Eligible applicants may also delay necessary healthcare until the Medicaid enrollment process is complete, which can increase their health risks and exacerbate any health conditions that they may have.

Retroactive eligibility allows patients who have been diagnosed with a serious illness, such as blood cancer, to begin treatment without being burdened by medical debt prior to their official eligibility determination. In Indiana, Medicaid recipients were responsible for an average of \$1,561 in medical costs with the elimination of retroactive eligibility.ⁱⁱⁱ Without retroactive eligibility, Medicaid enrollees could then face substantial costs at their doctor's office or pharmacy.

Patients with underlying health conditions who are unable to access regular care are often forced to go to emergency rooms and hospitals if their conditions worsen, leading health systems to provide more uncompensated care. For example, when Ohio was considering a similar provision in 2016, a consulting firm advised the state that hospitals could accrue as much as \$2.5 billion more in uncompensated care as a result of the waiver.^{iv} Increased uncompensated care costs are especially concerning as safety net hospitals and other providers continue to deal with limited resources and capacity during the COVID-19 pandemic. Limiting retroactive coverage increases the financial hardships to rural hospitals that absorb uncompensated care costs. LLS opposes the continued limitations to retroactive coverage and encourages the state to expand retroactive coverage to include all Medicaid beneficiaries.

EPSDT Benefit

LLS is opposed to the restricted coverage for treatment under Early and Periodic Screening, Diagnosis and Treatment (EPSDT). The purpose of the EPSDT benefit is to ensure that children receive appropriate healthcare, however, the limiting of that care to a prioritized list of services leaves families vulnerable to the cost of care for non-prioritized services or simply unable to access those needed services. Many of the services that have not been prioritized are for serious and concerning conditions, such as the special health care needs of children with cancer. In fact, blood cancers are among the most common pediatric cancers, with leukemia and lymphoma accounting for more than 1 in 3 cancer diagnoses among patients under the age of 20.^v These limitations to services can place low-income families under financial strain to cover the cost of necessary services that fall outside of the prioritized list.

While the state has demonstrated other efforts to increase equitable access to healthcare, the continued restriction of the EPSDT benefit is a step in the opposite direction. For example, children of color are enrolled in Medicaid at disproportionately higher rates^{vi} and as mentioned before, are also more likely to be affected by gaps in coverage.^{vii} These children are likely to be disproportionately affected by the limitations to the EPSDT benefit. LLS supports the removal of the restrictions to the EPSDT benefit to allow children full and equitable access to healthcare, in keeping with the purpose of the EPSDT benefit.

Conclusion

LLS believes that healthcare coverage should be affordable, accessible and adequate for children and adults with cancer. Questions or requests for further information on LLS and our position can be addressed to sara.kofman@lls.org.

Thank you for the opportunity to provide comments.

Sincerely,

Sara Kofman
Regional Director, Government Affairs
Leukemia & Lymphoma Society

ⁱ Osorio, Aubrianna. Alker, Joan, "Gaps in Coverage: A Look at Child Health Insurance Trends", Center for Children & Families (CCF) of the Georgetown University Health Policy Institute, November 21, 2021. [Gaps in Coverage: A Look at Child Health Insurance Trends – Center For Children and Families \(georgetown.edu\)](https://www.georgetown.edu/sites/georgetown.edu/files/2021-11/Gaps_in_Coverage_A_Look_at_Child_Health_Insurance_Trends_-_Center_For_Children_and_Families_(georgetown.edu).pdf)

ⁱⁱ <https://aspe.hhs.gov/sites/default/files/private/pdf/265366/medicaid-churning-ib.pdf>

ⁱⁱⁱ Healthy Indiana Plan 2.0 CMS Redetermination Letter. July 29, 2016. Available at: <https://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Waivers/1115/downloads/in/Healthy-Indiana-Plan-2/in-healthy-indiana-plan-support-20-lockouts-redetermination-07292016.pdf>

^{iv} Virgil Dickson, "Ohio Medicaid waiver could cost hospitals \$2.5 billion", Modern Healthcare, April 22, 2016.

(<http://www.modernhealthcare.com/article/20160422/NEWS/160429965>)

^v "Childhood and Adolescent Blood Cancer Facts and Statistics," The Leukemia & Lymphoma Society. Available at:

<https://www.lls.org/facts-and-statistics/childhood-and-adolescent-blood-cancer-facts-and-statistics>

^{vi} Brooks, Tricia. Whitener, Kelly. "At Risk: Medicaid's Child-Focused Benefit Structure Known as EPSDT," Center for Children & Families (CCF) of the Georgetown University Health Policy Institute, June 2017. EPSDT-At-Risk-Final.pdf (georgetown.edu)

^{vii} Osorio, Aubrianna. Alker, Joan, "Gaps in Coverage: A Look at Child Health Insurance Trends", Center for Children & Families (CCF) of the Georgetown University Health Policy Institute, November 21, 2021. [Gaps in Coverage: A Look at Child Health Insurance Trends – Center For Children and Families \(georgetown.edu\)](http://georgetown.edu)