



October 20, 2023

The Honorable Xavier Becerra, Health and Human Services Secretary
U.S. Department of Health and Human Services
200 Independence Avenue SW, Sixth Floor
Washington, DC 20201

Dear Secretary Becerra:

The State of Montana submits to the U.S. Department of Health and Human Services the enclosed Section 1115 demonstration waiver amendment application to add fertility preservation services to the 1115 Demonstration Waiver for Additional Services and Populations (WASP).

During the 2023 Montana Legislative Session, Senate Bill 516 to "Provide for the Preserving Fertility Act," was passed and signed into law by Governor Gianforte. This legislation requires the Montana Department of Public Health and Human Services (DPHHS) to add Medicaid and the Children's Health Insurance Program (CHIP), also known in Montana as Healthy Montana Kids (HMK), coverage for fertility preservation services for aged-eligible individuals diagnosed with cancer and the standard of care involves medical treatment that may directly or indirectly cause iatrogenic infertility.

In light of the statutory directive, Montana DPHHS seeks approval from the Centers for Medicare and Medicaid Services (CMS) to amend the Section 1115 Montana WASP to add fertility preservation services for age eligible Medicaid and CHIP/HMK enrolled members diagnosed with cancer effective January 1, 2024.

The WASP is a statewide Section 1115 Medicaid demonstration waiver that was first approved in 1996. This waiver has historically provided an eligibility pathway for low-income individuals living with a severe mental illness (SMI) not otherwise eligible for Medicaid; and unlimited dental treatment services for Aged/Blind/Disabled Medicaid enrollees.

On August 19, 2023, DPHHS began the extensive state-level, 60-day public noticing process with all Montanans, including healthcare organizations, advocacy groups, and Medicaid members and their families. This included a presentation to the Children, Families, Health and Human Services Interim Committee on September 12, 2023, and a public hearing held on September 15, 2023. DPHHS also informed Tribal Governments, Urban Indian Organizations, and Indian Health Service via a tribal consultation letter mailed on August 17, 2023.

On behalf of all Montanans, I look forward to collaborating with CMS on getting the WASP 1115 Demonstration Waiver amendment adding fertility preservation services approved in a timely manner.

Sincerely,



Mike Randol

Montana Department of Public Health and Human Services
Medicaid and Health Services Executive Director/State Medicaid Director

- C: Daniel Tsai, M.D., CMS
- Anne Marie Costello, CMS
- Teresa DeCaro, CMS
- Mehreen Rashid, CMS
- Chiquita Brooks-LaSure, CMS



Montana Department of Public Health and Human Services

Section 1115 Demonstration Amendment/Extension

Fast-Track Extension Application for Program Changes

***Montana Waiver for Additional Services and Populations (WASP)
Demonstration Program***

October 20, 2023

**Montana Department of Public Health and Human Services
Section 1115 Demonstration Amendment Application**

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Proposed Demonstration Changes for the Extension Period

A. General Description

Summary of Proposed Changes

During the 2023 Montana Legislative Session, Senate Bill 516¹ "Provide for the preserving Fertility Act" was passed and signed into law by Governor Gianforte. This legislation requires the Montana Department of Public Health and Human Services (DPHHS) to add Medicaid and the Children's Health Insurance Program (CHIP), also known in Montana as Healthy Montana Kids (HMK), coverage for fertility preservation services for aged-eligible individuals diagnosed with cancer and the standard of care involves medical treatment that may directly or indirectly cause iatrogenic infertility.

In light of the statutory directive, Montana DPHHS seeks approval from the Centers for Medicare and Medicaid Services (CMS) to amend the Section 1115 Montana Waiver for Additional Services and Populations Demonstration Waiver to add fertility preservation services for age eligible Medicaid and CHIP/HMK enrolled members diagnosed with cancer effective January 1, 2024.

Goals and Objectives

Under Section 1115 of the Social Security Act, States may implement "experimental, pilot or demonstration projects which, in the judgment of the Secretary [of Health and Human Services] is likely to assist in promoting the objectives of [Medicaid]". The State believes this demonstration is likely to promote the objectives of Medicaid by improving participant health outcomes and quality of life. Providing these services will make it possible for Medicaid and CHIP/HMK eligible individuals who have been diagnosed with a form of cancer, and whose related treatment may cause a substantial risk of sterility or iatrogenic infertility (including surgery, radiation, or chemotherapy) to receive coverage for fertility preservation services.

B. Expenditure Authorities.

Montana is requesting expenditure authority under Section 1115 to provide fertility preservation services for Medicaid and CHIP/HMK eligible individuals between the age of 12 and 35 with an active diagnosis of cancer where the treatment would put them at risk for infertility. The requested expenditure authority promotes the objectives of Title XIX by improving health outcomes for Medicaid and CHIP/HMK populations.

This amendment request does not propose any additional waiver and expenditure authority changes to the WASP Demonstration Program beyond what is in the extension/renewal for the Section 1115 WASP approved on November 21, 2022.

Montana intends to continue to provide standard Medicaid benefits for up to 3,000 WMHSP individuals including 12 months continuous coverage. Additionally, the WASP will continue to cover individuals determined categorically eligible for ABD for dental treatment services above the Medicaid State Plan cap of \$1,125.

¹ SB 516 available at [SB0516.pdf \(mt.gov\)](https://legis.mt.gov/bills/500/516).

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C. Waiver Authorities.

As directed by statute, DPHHS is seeking the addition of fertility preservation expenditure authority from its 1115 WASP approved on November 21, 2022, for age-eligible Medicaid and CHIP/HMK members diagnosed with cancer and the standard of care involves medical treatment that may directly or indirectly cause iatrogenic infertility.

The State requests the following proposed waiver and expenditure authority to operate the fertility preservation services under the WASP 1115 demonstration.

Waiver and Expenditure Authority	Reason and Use of Waiver
Section 1902(a)(10)(B)- Amount, Duration, and Scope of Services and Comparability	To enable the State to vary the amount, duration, and scope of services provided to individuals in the demonstration group.

D. Eligibility

Fertility preservation services included under this Demonstration are available to Medicaid and CHIP/HMK eligible individuals who are:

- diagnosed by a physician as having an active cancer diagnosis requiring treatment that may cause a substantial risk of sterility or iatrogenic infertility (infertility caused by cancer treatment); and
- between the ages of 12 and 35.

Medicaid and CHIP/HMK members will qualify for fertility preservation services outlined in this Demonstration based upon their medical need for services. Eligibility requirements will not differ from the approved Medicaid and CHIP State Plans, Alternative Benefit Plan and the WMHSP population receiving standard Medicaid through this 1115 waiver Demonstration. DPHHS is not proposing changes to Medicaid or CHIP/HMK eligibility standards in this Demonstration application.

The eligibility groups outlined in the table below will not be eligible for fertility preservations services as they receive limited Medicaid benefits only.

Eligibility Group Name	Social Security Act and CFR Citations
Qualified Medicare Beneficiaries (QMB)	1902(a)(10)(E)(i) 1905(p)
Specified Low Income Medicare Beneficiaries (SLMB)	1902(a)(10)(E)(iii)
Qualified Individual (QI) Program	1902(a)(19)(E)(iv)
Family Planning – Authorized through Montana’s Plan First §1115 Family Planning Demonstration	1902(a)(10)(A)(ii)(XXI)

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Projected Enrollment

The State is not proposing any changes to Medicaid eligibility requirements in the Section 1115 Demonstration change request. As such, the Demonstration is not expected to affect enrollment trends, which will continue to be determined largely by demographic changes and economic conditions. The projected enrollment for the demonstration population is approximately 35-40 Medicaid and 1-5 CHIP/HMK members per year will utilize the fertility preservation benefit. Members are limited to one benefit per lifetime.

E. Benefits and Cost Sharing

Benefits

If approved under this demonstration, qualified Medicaid and CHIP/HMK members will be eligible to receive the following services:

- Collection of eggs and sperm consistent with established medical practices or professional guidelines published by the American Society of Reproductive Medicine or the American Society of Clinical Oncology.

Under this amendment application, Montana intends to continue the following current Demonstration features including:

- Coverage of the Standard Medicaid benefits package for WMHSP.
 - Covered individuals age 18 or older with SDMI who are otherwise ineligible for Medicaid benefits and either:
 - Have income 0-138% of the FPL and are eligible for or enrolled in Medicare; or
 - Have income 139-150% of the FPL regardless of Medicare status.
 - 12-month continuous coverage for the WMHSP population.
- Dental treatment services above the dental treatment services annual cap outlined in the Medicaid State Plan for the ABD population. (Covered dental treatment services, excluding diagnostic, preventive, denture and anesthesia services for adults age 21 and over, are subject to the annual cap of \$1,125 in the State Plan.)

Cost Sharing

If approved under this demonstration, cost sharing/copayment requirements for Medicaid fertility preservation services will not differ from those provided under the Medicaid state plan. Montana does not require cost sharing or copayments for any Medicaid covered service.

Individuals enrolled in CHIP/HMK will be assessed copayments for fertility preservation services in line with the current approved CHIP/HMK state plan. Fertility preservation services are subject to annual deductibles and copayment provisions as applicable to hospital, medical, or surgical services covered under the state plan.

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F. Delivery System.

The State does not propose any changes to the Medicaid health care delivery system. The new fertility preservation services for the demonstration individuals will be provided through the current fee for service (FFS) reimbursement system. All enrollees will continue to receive services through their current delivery system in the same manner under the state’s current state plan.

The State does not propose any changes to the CHIP/HMK health care delivery system. Fertility preservation services will be provided through the current Third Party Administrator (TPA) fee for service contract. All enrollees will continue to receive services through their current delivery system in the same manner under the state’s current state plan.

G. Budget/Allotment Neutrality.

Enrollment Projections and Annual Expenditures

Montana developed projections for the demonstration period based on state historical expenditures, as available, as well as anticipated cost and utilization trends. Below is the projected enrollment and expenditures for the remaining demonstration years:

	DY21 (2024)	DY22 (2025)	DY23 (2026)	DY24 (2027)
Medicaid Enrollment	15	15	16	16
Medicaid Expenditures	121,838	125,493	137,875	142,012
Expansion Enrollment	21	21	22	23
Expansion Expenditures	170,574	175,691	189,579	204,142
CHIP Enrollment	1	1	1	1
CHIP Expenditures	8,123	8,366	8,617	8,876

The projected fertility preservation enrollment and expenditures results in an estimated fiscal impact of \$1,301,185 for the remaining 4 demonstrations years.

H. Evaluation.

The State will develop a plan for evaluating the hypothesis indicated below. Montana will identify validated performance measures that adequately assess the impact of these demonstrations to beneficiaries. The State will submit the revised evaluation design to CMS for approval. The State will conduct ongoing monitoring of this demonstration, and will provide information regarding monitoring activities in the required monitoring reports. The following hypothesis will be tested during the approval period.

Hypothesis	Anticipated Measure(s)	Data Sources	Evaluation Approach
This demonstration will allow individuals who are at risk for infertility due to cancer treatment to preserve their ability to have children in the future.	Number of individuals served under this demonstration	MMIS Data Warehouse	Montana will design quantitative and qualitative measures to include quasi-experimental comparisons.

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I. Compliance with Public Notice Process

Public Notice Process

To be completed after state notice and public comment period concludes.

State Contact Person(s)

Please provide the contact information for the state's point of contact for this demonstration extension application.

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WASP Fertility Preservation Amendment Public Comments

September 12, 2023 CFHHS Interim Committee meeting:

Comment: Senator Gross, a CFHHS Interim Committee member indicated this amendment arises out of a bill she sponsored, and the legislature approved. She asked whether Montana will be the first state with such a waiver amendment and how confident the state is that it will be approved.

Response: The state of Utah has submitted an amendment to one of their 1115 waivers with similar requests. The Utah waiver was submitted in 2021 and still shows as “pending”. The Utah waiver covers more extensive services regarding fertility preservation than the Montana amendment does. It is unclear what the timeline will be for approval of this amendment. Montana may face challenges if we are setting a precedent as we negotiate STC’s (Special Terms and Conditions), review budget neutrality, etc. with CMS. However, DPHHS expressed confidence in receiving approval; it is just a matter of the length of the timeline to get there.

Comment: Senator Dunwell thanked DPHHS for “going out on a limb” to pursue this amendment. Young people who have been diagnosed with cancer and are undergoing treatment do not need the additional stress of wondering if they will still be able to have children in the future. Fertility preservation services will give them more reason to fight the disease.

Response: We thank the commentator for their support of this amendment.

September 15, 2023 Public Meeting:

Comment: Bobbie Will, Susan G. Komen Foundation asked what happens to fertility preservation after the 2028 waiver demonstration end date.

Response: Currently, DPHHS does not have any plans to terminate the WASP waiver. We have recently received an extension on the waiver that extends until 2028. At this time, the goal is to continue these services in the waiver, including fertility preservation, and request CMS approval to renew the waiver in 2028.

Email Responses:

Comment:

Thank you for the opportunity to provide feedback on the Montana Section 1115 WASP amendment adding fertility preservation.

The undersigned organizations advocate on behalf of more than 7,000 individuals in Montana who will be diagnosed with cancer and more than 2,000 that will die in 2023 alone. We support the proposed WASP amendment adding fertility preservation

Certain cancer treatments can directly or indirectly cause medically necessary induced infertility. Chemotherapy, radiation, and surgery can cause permanent damage to gametes, reproductive organs and/or endocrine functioning. For many cancer patients, fertility concerns are a major factor influencing their treatment decisions. Patients often have a short window of time to obtain the financial resources necessary to preserve fertility before starting potentially sterilizing cancer treatments.

Our organizations believe this proposal will promote the objectives of Medicaid by improving participant health outcomes and quality of life. The proposed amendment will allow eligible individuals who have been diagnosed with cancer, and whose related treatments may cause a substantial risk of sterility or iatrogenic infertility, to receive coverage for fertility preservation services.

Given the vital impact on the quality of life for cancer patients, our organizations support the proposed amendment.

Thank you for the opportunity to provide feedback.

Sincerely,

American Cancer Society, Cancer Support Community Montana, and Susan G. Komen

Response:

DPHHS appreciates the commenters support for this amendment and for supporting the population being represented in this amendment.

Comment:

Hello DPHHS,

I would like to provide this official public comment to support the January 2024 CMS Medicaid Waiver for Additional Services and Populations (WASP) Amendment to add fertility preservation for oncology patients.

During the legislative session, as a state Senator, I voted in favor of passage of SB 516, the bill leading to this waiver amendment. I believe and the legislature found that future fertility is a top quality of life priority for many young cancer patients and that the possibility of infertility may cause significant distress and grief during a time when cancer patients are also facing not only their diagnoses but also the prospects of treatment that may include surgery, chemotherapy, radiation, or a combination of those approaches.

The legislature further agreed that fertility preservation is medically necessary and considered part of the standard of care for age-eligible oncology patients.

Thank you for considering this public comment asking for the CMS Medicaid Waiver for Fertility Preservation for WASP.

Warm regards,

Mary Ann
Sen. Mary Ann Dunwell

Response: We thank this commenter for supporting DPHHS regarding this amendment and for supporting the population it is representing.