DEPARTMENT OF SOCIAL SERVICES

Notice of Proposed Medicaid State Plan Amendment (SPA)

SPA 22-F: Mandatory Medicaid Coverage of Routine Patient Costs Furnished in Connection with Participation in Qualifying Clinical Trials

The State of Connecticut Department of Social Services (DSS) proposes to submit the following Medicaid State Plan Amendment (SPA) to the Centers for Medicare & Medicaid Services (CMS) within the U.S. Department of Health and Human Services (HHS).

Changes to Medicaid State Plan

Effective on or after January 1, 2022, SPA 22-F will amend Attachments 3.1-A, 3.1-B, and 4.19-B of the Medicaid State Plan in order to add coverage and payment provisions to the Medicaid State Plan for the new mandatory benefit category to provide coverage of routine patient costs provided to Medicaid members participating in qualifying clinical trials.

Specifically, effective for items or services furnished on or after January 1, 2022, federal law in Division CC, Title II, Section 210 of the Consolidated Appropriations Act, 2021 (Public Law 116-260) amended section 1905(a) of the Social Security Act ("Act") by adding to the definition of medical assistance a new mandatory Medicaid State Plan benefit category in section 1905(a)(30) for routine patient costs for items and services furnished in connection with participation by Medicaid beneficiaries in qualifying clinical trials, subject to further provisions in a new section 1905(gg) of the Act. Federal law was also amended to make this benefit mandatory under any benchmark plan, also known as an Alternative Benefit Plan (ABP), which in Connecticut's Medicaid program is the benefit package provided to the Medicaid expansion population or HUSKY D. Accordingly, DSS will also submit a SPA to amend the ABP to add this benefit category, which will be in SPA 22-H.

As set forth in the federal law referenced above and as further detailed in the CMS State Medicaid Director Letter (SMD) # 21-005 dated December 7, 2021, this new benefit category includes only routine patient costs as defined in that federal law that would otherwise be covered under the Medicaid State Plan, waiver, or demonstration waiver under section 1115 of the Act and do not include any investigational item or service that is the subject of the qualifying clinical trial and not otherwise covered under the state plan, waiver, or demonstration waiver. This coverage category also applies only to qualifying clinical trials that meet the specifications set forth in the federal law referenced above. Given that the federal requirements provide only for coverage and payment for otherwise covered services, this SPA will specify that the services covered and the payment methodology will remain the same as the underlying services. Therefore, DSS does not anticipate any substantive change in coverage or payment, nor does DSS anticipate that this SPA will change Medicaid expenditures.

Fee schedules are published at this link: http://www.ctdssmap.com, then select "Provider", then select "Provider Fee Schedule Download", then Accept or Decline the Terms and Conditions and then select the applicable fee schedule.

Fiscal Impact

As explained above, DSS does not anticipate that this SPA will have any significant in annual aggregate expenditures in State Fiscal Year (SFY) 2022 and SFY 2023.

Obtaining SPA Language and Submitting Comments

The proposed SPA is posted on the DSS website at this link: https://portal.ct.gov/DSS/Health-And-Home-Care/Medicaid-State-Plan-Amendments. The proposed SPA may also be obtained at any DSS field office, at the Town of Vernon Social Services Department, or upon request from DSS (see below).

To request a copy of the SPA from DSS or to send comments about the SPA, please email: Public.Comment.DSS@ct.gov or write to: Department of Social Services, Medical Policy Unit, 55 Farmington Avenue, 9th Floor, Hartford, CT 06105. Please reference "SPA 22-F: Mandatory Medicaid Coverage of Routine Patient Costs Furnished in Connection with Participation in Qualifying Clinical Trials."

Anyone may send DSS written comments about this SPA. Written comments must be received by DSS at the above contact information no later than January 12, 2022.

State: Connecticut

Amount, Duration, and Scope of Services Provided to Categorically Needy Group(s): ALL

Coverage of Routine Patient Costs Associated with Participation in Qualifying Clinical Trials (Section 1905(a)(30))

Citation: 3.1(a)(1) Amount, Duration, and Scope of Services: Categorically Needy (Continued)

1905(a)(30) __X__ coverage of routine patient costs associated with participation in qualifying clinical trials as described and limited in the Addendum to Attachment 3.1-A.

ATTACHMENT 3.1-A identifies the medical and remedial services provided to the categorically needy.

State: Connecticut
Amount, Duration, and Scope of Services Provided to Categorically Needy Group(s): ALL

Section 1905(a)(30) – Coverage of Routine Patient Costs Associated with Participation in Qualifying Clinical Trials

1. **Assurances**: Coverage of routine patient costs associated with participation in qualifying clinical trials is provided under the Medicaid state plan with respect to items and services furnished to Medicaid beneficiaries who are participating in a qualifying clinical trial on or after January 1, 2022. The state also has a process for an expedited coverage determination process that complies with section 1905(gg)(3) of the Act.

2. **Covered Services**: Any item or service provided to the individual under the qualifying clinical trial as defined in section 1905(gg)(2) of the Act, including any item or service provided to prevent, diagnose, monitor, or treat complications resulting from participation in the qualifying clinical trial (and also any item or service required solely for the provision of the investigational item or service that is the subject of the qualifying clinical trial, including the administration of the investigational item or service), but only to the extent that the provision of such items or services to the beneficiary would otherwise be covered outside the course of participation in the qualifying clinical trial under the Medicaid state plan or waiver, including a demonstration project under section 1115 of the Act.

3. **Limitations**: This benefit does not include any investigational item or service that: (a) is the subject of the qualifying clinical trial and is not otherwise covered outside of the clinical trial under the state plan, waiver, or demonstration project or (b) is solely to satisfy data collection and analysis for the qualifying clinical trial that is not used in the direct clinical management of the beneficiary and is not otherwise covered under the state plan, waiver, or demonstration project.

4. **Alignment with Underlying Benefits**: Except as otherwise specifically provided in this section or required by sections 1905(a)(30) and 1905(gg), all services provided under this benefit follow the same provisions, requirements, and limitations set forth in the applicable section of Attachment 3.1-A of the Medicaid State Plan (or, to the extent applicable, in the relevant waiver or demonstration project).

State: Connecticut

Amount, Duration, and Scope of Services Provided to Medically Needy Group(s): ALL

Coverage of Routine Patient Costs Associated with Participation in Qualifying Clinical Trials (Section 1905(a)(30))

Citation: 3.1(b)(1) Amount, Duration, and Scope of Services: Medically Needy (Continued)

1905(a)(30) __X__ coverage of routine patient costs associated with participation in qualifying clinical trials as described and limited in the Addendum to Attachment 3.1-B.

ATTACHMENT 3.1-B identifies the medical and remedial services provided to the medically needy.

State: Connecticut

Amount, Duration, and Scope of Services Provided to Medically Needy Group(s): ALL

Section 1905(a)(30) – Coverage of Routine Patient Costs Associated with Participation in Qualifying Clinical Trials

1. **Assurances**: Coverage of routine patient costs associated with participation in qualifying clinical trials is provided under the Medicaid state plan with respect to items and services furnished to Medicaid beneficiaries who are participating in a qualifying clinical trial on or after January 1, 2022. The state also has a process for an expedited coverage determination process that complies with section 1905(gg)(3) of the Act.

2. **Covered Services**: Any item or service provided to the individual under the qualifying clinical trial as defined in section 1905(gg)(2) of the Act, including any item or service provided to prevent, diagnose, monitor, or treat complications resulting from participation in the qualifying clinical trial (and also any item or service required solely for the provision of the investigational item or service that is the subject of the qualifying clinical trial, including the administration of the investigational item or service), but only to the extent that the provision of such items or services to the beneficiary would otherwise be covered outside the course of participation in the qualifying clinical trial under the Medicaid state plan or waiver, including a demonstration project under section 1115 of the Act.

3. **Limitations**: This benefit does not include any investigational item or service that: (a) is the subject of the qualifying clinical trial and is not otherwise covered outside of the clinical trial under the state plan, waiver, or demonstration project or (b) is solely to satisfy data collection and analysis for the qualifying clinical trial that is not used in the direct clinical management of the beneficiary and is not otherwise covered under the state plan, waiver, or demonstration project.

4. **Alignment with Underlying Benefits**: Except as otherwise specifically provided in this section or required by sections 1905(a)(30) and 1905(gg), all services provided under this benefit follow the same provisions, requirements, and limitations set forth in the applicable section of Attachment 3.1-A of the Medicaid State Plan (or, to the extent applicable, in the relevant waiver or demonstration project).

State: Connecticut

30. Coverage of Routine Patient Costs Associated with Participation in Qualifying Clinical Trials Pursuant to Section 1905(a)(30) of the Social Security Act

Coverage of routine patient costs associated with participation in qualifying clinical trials is provided under the Medicaid state plan with respect to items and services furnished to Medicaid beneficiaries who are participating in a qualifying clinical trial pursuant to section 1905(a)(30) of the Social Security Act is reimbursed in accordance with the applicable provision of the Medicaid State Plan, waiver, or demonstration project, as applicable to the provider category and the category of service, including, but not limited to, as applicable, the relevant section or sections of Attachments 4.19-A or 4.19-B of the Medicaid State Plan.