Table of Contents

State/Territory Name: Connecticut

State Plan Amendment (SPA) #: 22-0010

This file contains the following documents in the order listed:

- 1) Approval Letter
- 2) CMS-179
- 3) Approved SPA Pages



Medicaid and CHIP Operations Group

May 9, 2022

Dr. Deidre Gifford, Commissioner Department of Social Services 55 Farmington Avenue Hartford, CT 06105

Re: Connecticut State Plan Amendment (SPA) 22-0010

Dear Commissioner Gifford:

We reviewed your proposed Medicaid State Plan Amendment (SPA) submitted under transmittal number (TN) 22-0010. This amendment updates the state plan to add mandatory coverage of routine patient costs furnished in connection with participation in qualifying clinical trials.

We conducted our review of your submittal according to statutory requirements in Title XIX of the Social Security Act and implementing regulations 1905(a)(30) and 1905(gg). This letter is to inform you that Connecticut Medicaid SPA Transmittal Number 22-0010 was approved on May 3, 2022 with an effective date of January 1, 2022.

If you have any questions, please contact Marie DiMartino at 617-565-9157 or via email at Marie.DiMartino@cms.hhs.gov.

Sincerely,



James G. Scott, Director Division of Program Operations

| TRANSMITTAL AND NOTICE OF APPROVAL OF STATE PLAN MATERIAL FOR: CENTERS FOR MEDICARE & MEDICAID SERVICES | 1. TRANSMITTAL NUMBER 2. STATE 2 2 0 0 1 0 |
|---|---|
| | 3. PROGRAM IDENTIFICATION: TITLE OF THE SOCIAL SECURITY ACT O XIX O XXI |
| TO: CENTER DIRECTOR CENTERS FOR MEDICAID & CHIP SERVICES DEPARTMENT OF HEALTH AND HUMAN SERVICES | 4. PROPOSED EFFECTIVE DATE January 1, 2022 |
| 5. FEDERAL STATUTE/REGULATION CITATION Social Security Act Sections 1905(a)(30) and 1905(gg) | 6. FEDERAL BUDGET IMPACT (Amounts in WHOLE dollars) a FFY 2022 \$ 0 b. FFY 2023 \$ 0 |
| 7. PAGE NUMBER OF THE PLAN SECTION OR ATTACHMENT | 8. PAGE NUMBER OF THE SUPERSEDED PLAN SECTION OR ATTACHMENT (If Applicable) |
| Attachment 3.1-A, Page 12b Attachment 3.1-B, Page 11b Attachment 4.19-B, Page 48 | NEW NEW NEW |
| 9. SUBJECT OF AMENDMENT This SPA adds coverage and payment provisions for the new mandatory Medicaid State Plan benefit category for routine patient costs for items and services furnished in connection with participation by Medicaid beneficiaries in qualifying clinical trials. The services covered and payment methodology are the same as in the underlying federal state plan or other authority. 10. GOVERNOR'S REVIEW (Check One) © GOVERNOR'S OFFICE REPORTED NO COMMENT © GOVERNOR'S OFFICE REPORTED NO COMMENT © OTHER, AS SPECIFIED: O OTHER, AS SPECIFIED: | |
| | 5. RETURN TO tate of Connecticut |
| Deidre S. Gifford, MD, MPH | epartment of Social Service 5 Farmington Avenue, 9th Floor artford, CT 06105 ttention: Ginny Mahoney |
| FOR CMS USE ONLY | |
| March 30, 2022 | 7. DATE APPROVED May 3, 2022 |
| PLAN APPROVED - ONE COPY ATTACHED | |
| 18. EFFECTIVE DATE OF APPROVED MATERIAL January 1 2022 | |
| 20. TYPED NAME OF APPROVING OFFICIAL 2 James G. Scott | 1. TITLE OF APPROVING OFFICIAL Director Division of Program Operations |
| 22. REMARKS | |

ATTACHMENT 3.1-A

Page 12b

State/Territory: <u>Connecticut</u>

AMOUNT, DURATION AND SCOPE OF SERVICES PROVIDED

CATEGORICALLY NEEDY GROUP(S)

30. Coverage of Routine Patient Cost in Qualifying Clinical Trials

*The state needs to check each assurance below.

Provided: \underline{X}

I. General Assurances:

Routine Patient Cost – Section 1905(gg)(1)

 \underline{X} Coverage of routine patient cost for items and services as defined in section 1905(gg)(1) that are furnished in connection with participation in a qualified clinical trial.

Qualifying Clinical Trial – Section 1905(gg)(2)

<u>X</u> A qualified clinical trial is a clinical trial that meets the definition at section 1905(gg)(2).

Coverage Determination – Section 1905(gg)(3)

 \underline{X} A determination with respect to coverage for an individual participating in a qualified clinical trial will be made in accordance with section 1905(gg)(3).

PRA Disclosure Statement - This information is being collected to assist the Centers for Medicare & Medicaid Services in implementing Section 210 of the Consolidated Appropriations Act of 2021 amending section 1905(a) of the Social Security Act (the Act), by adding a new mandatory benefit at section 1905(a)(30). Section 210 mandates coverage of routine patient services and costs furnished in connection with participation by Medicaid beneficiaries in qualifying clinical trials effective January 1, 2022. Section 210 also amended sections 1902(a)(10)(A) and 1937(b)(5) of the Act to make coverage of this new benefit mandatory under the state plan and any benchmark or benchmark equivalent coverage (also referred to as alternative benefit plans, or ABPs). Under the Privacy Act of 1974 any personally identifying information obtained will be kept private to the extent of the law. An agency may notconduct or sponsor, and a person is not required to respond to, a collection of information unlessit displays a currently valid Office of Management and Budget (OMB) control number. The OMB control number for this project is 0938-1148 (CMS-10398 #74). Public burden for all of the collection of information requirements under this control number is estimated to take about 56 hours per response. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to CMS, 7500 SecurityBoulevard, Attn: Paperwork Reduction Act Reports Clearance Officer, Mail Stop C4-26-05, Baltimore, Maryland 21244-1850.

TN: <u>22-0010</u> Supersedes TN: <u>NEW</u>

Approval Date: <u>05/03/2022</u>

Effective Date: 01/01/2022

ATTACHMENT 3.1-B

Page 11b

State/Territory: Connecticut

AMOUNT, DURATION AND SCOPE OF SERVICES PROVIDED

MEDICALLY NEEDY GROUP(S)

30. Coverage of Routine Patient Cost in Qualifying Clinical Trials

*The state needs to check each assurance below.

Provided: \underline{X}

I. General Assurances:

Routine Patient Cost – Section 1905(gg)(1)

<u>X</u> Coverage of routine patient cost for items and services as defined in section 1905(gg)(1) that are furnished in connection with participation in a qualified clinical trial.

Qualifying Clinical Trial – Section 1905(gg)(2)

<u>X</u> A qualified clinical trial is a clinical trial that meets the definition at section 1905(gg)(2).

Coverage Determination – Section 1905(gg)(3)

 \underline{X} A determination with respect to coverage for an individual participating in a qualified clinical trial will be made in accordance with section 1905(gg)(3).

PRA Disclosure Statement - This information is being collected to assist the Centers for Medicare & Medicaid Services in implementing Section 210 of the Consolidated Appropriations Act of 2021 amending section 1905(a) of the Social Security Act (the Act), by adding a new mandatory benefit at section 1905(a)(30). Section 210 mandates coverage of routine patient services and costs furnished in connection with participation by Medicaid beneficiaries in qualifying clinical trials effective January 1, 2022. Section 210 also amended sections 1902(a)(10)(A) and 1937(b)(5) of the Act to make coverage of this new benefit mandatory under the state plan and any benchmark or benchmark equivalent coverage (also referred to as alternative benefit plans, or ABPs). Under the Privacy Act of 1974 any personally identifying information obtained will be kept private to the extent of the law. An agency may notconduct or sponsor, and a person is not required to respond to, a collection of information unlessit displays a currently valid Office of Management and Budget (OMB) control number. The OMB control number for this project is 0938-1148 (CMS-10398 #74). Public burden for all of the collection of information requirements under this control number is estimated to take about 56 hours per response. Send comments regarding this burden estimate or any other aspect of this collection of fin formation, including suggestions for reducing this burden, to CMS, 7500 SecurityBoulevard, Attn: Paperwork Reduction Act Reports Clearance Officer, Mail Stop C4-26-05, Baltimore, Maryland 21244-1850.

TN: <u>22-0010</u> Supersedes TN: <u>NEW</u>

Approval Date: <u>05/03/2022</u>

Effective Date: 01/01/2022

STATE PLAN UNDER TITLE XIX OF THE SOCIAL SECURITY ACT State: <u>Connecticut</u>

Methods and Standards for Establishing Rates - Other Types of Care

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 is provided under the Medicaid State Plan for routine patient costs associated with 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. Such coverage is reimbursed in accordance with the applicable provision of the Medicaid State Plan, waiver, or demonstration project, for the applicable provider category and category of service, including, but not limited to, the relevant section or sections of Attachments 4.19-A or 4.19-B of the Medicaid State Plan.

Approval Date 05/03/22

Effective Date: 01/01/2022

TN # <u>22-0010</u> Supersedes TN # <u>NEW</u>