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State/Territory Name: Massachusetts

State Plan Amendment (SPA) #: 22-0006

This file contains the following documents in the order listed:

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

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
601 E. 12th St., Room 355
Kansas City, Missouri 64106



Medicaid and CHIP Operations Group

May 10, 2022

MaryLou Sudders, Secretary
The Commonwealth of Massachusetts
Executive Office of Health and Human Services
Office of Medicaid
One Ashburton Place, Room 1109
Boston, MA 02108

Re: Massachusetts State Plan Amendment (SPA) 22-0006

Dear Secretary Sudders:

We reviewed your proposed Medicaid State Plan Amendment (SPA) submitted under transmittal number (TN) 22-0006. 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 Massachusetts Medicaid SPA Transmittal Number 22-0006 was approved on May 10, 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 <u>2 2 - 0 0 0 6</u>	2. STATE <u>MA</u>
3. PROGRAM IDENTIFICATION: TITLE <u>XIX</u> OF THE SOCIAL SECURITY ACT	
4. PROPOSED EFFECTIVE DATE <u>01/01/2022</u>	
6. FEDERAL BUDGET IMPACT (Amounts in WHOLE dollars) a FFY <u>22</u> \$ <u>0</u> b FFY <u>23</u> \$ <u>0</u>	
8. PAGE NUMBER OF THE SUPERSEDED PLAN SECTION OR ATTACHMENT (If Applicable)	

TO: CENTER DIRECTOR
CENTERS FOR MEDICAID & CHIP SERVICES
DEPARTMENT OF HEALTH AND HUMAN SERVICES

5. FEDERAL STATUTE/REGULATION CITATION
42 U.S.C. 1396d(gg); 42 CFR Part 447

7. PAGE NUMBER OF THE PLAN SECTION OR ATTACHMENT
Attachment 3.1-A p.13 (NEW)
Attachment 3.1-B p. 12 (NEW)
Attachment 4.19-B p. 3.4 (NEW)

9. SUBJECT OF AMENDMENT
An amendment confirming coverage of routine patient costs for services furnished in connection with participation by Medicaid beneficiaries in qualifying clinical trials

10. GOVERNOR'S REVIEW (Check One)

<input type="checkbox"/> GOVERNOR'S OFFICE REPORTED NO COMMENT	<input checked="" type="checkbox"/> OTHER, AS SPECIFIED: <u>Not required under 42 CFR 430.12(b)(2)(i)</u>
<input type="checkbox"/> COMMENTS OF GOVERNOR'S OFFICE ENCLOSED	
<input type="checkbox"/> NO REPLY RECEIVED WITHIN 45 DAYS OF SUBMITTAL	

12. TYPED NAME
Marylou Sudders

13. TITLE
Secretary

14. DATE SUBMITTED
03/31/22

15. RETURN TO
The Commonwealth of Massachusetts
Executive Office of Health and Human Services
Office of Medicaid
One Ashburton Place, Room 1109
Boston, MA 02108

FOR CMS USE ONLY

16. DATE RECEIVED <u>March 31, 2022</u>	17. DATE APPROVED <u>May 10, 2022</u>
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PLAN APPROVED - ONE COPY ATTACHED

18. EFFECTIVE DATE OF APPROVED MATERIAL
January 1, 2022

20. TYPED NAME OF APPROVING OFFICIAL
James G. Scott

21. TITLE OF APPROVING OFFICIAL
Director,
Division of Program Operations

22. REMARKS

State Plan under Title XIX of the Social Security Act
State: Massachusetts
Amount, Duration, and Scope of Medical
and Remedial Care and Services Provided to the Categorically Needy

30. Coverage of Routine Patient Cost in Qualifying Clinical Trials

*The state needs to check each assurance below.

Provided: X

I. General Assurances:

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

 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)

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

Coverage Determination – Section 1905(gg)(3)

 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).

State Plan under Title XIX of the Social Security Act
State: Massachusetts
Amount, Duration, and Scope of Medical
and Remedial Care and Services Provided to the Medically Needy

30. Coverage of Routine Patient Cost in Qualifying Clinical Trials

*The state needs to check each assurance below.

Provided: X

I. General Assurances:

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

 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)

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

Coverage Determination – Section 1905(gg)(3)

 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).

State Plan under Title XIX of the Social Security Act
State: Massachusetts
Methods and Standards for Establishing Payment Rates – Other Types of Care

1905(a)(30) routine patient costs for items and services furnished in connection with participation in a qualifying clinical trial

Routine patient costs for items and services furnished in connection with participation in a qualifying clinical trial, as defined in Section 1905(gg), shall be reimbursed using the same methodology as described in Attachments 4.19-A and 4.19-B for the applicable item or service.