PUBLIC NOTICE

December 17, 2021

Pursuant to 42 C.F.R. Section 447.205, public notice is hereby given for the submission of a Medicaid State Plan Amendment (SPA) 21-0052 Clinical Trial Costs. The Division of Medicaid, in the Office of the Governor, will submit this proposed SPA to the Centers for Medicare and Medicaid Services (CMS) effective January 1, 2022, contingent upon approval from CMS, our Transmittal #21-0052.

1. Mississippi Medicaid SPA 21-0052 Clinical Trial Cost is being submitted to comply with Section 210 of the Consolidated Appropriations Act, 2021, which added a mandatory benefit for routine patient costs for items and services furnished in connection with participation by Medicaid beneficiaries in qualifying clinical trials.

2. There is no data currently available regarding Mississippi Medicaid beneficiaries participating in qualifying clinical trials. The Division of Medicaid does not currently identify or deny medically necessary services associated with clinical trials and does not have an estimated aggregate impact for this change.

3. The Division of Medicaid is submitting this proposed SPA to be in compliance with the Consolidated Appropriations Act, 2021.

4. A copy of the proposed SPA will be available in each county health department office and in the Department of Human Services office in Issaquena County for review. A hard copy can be downloaded and printed from www.medicaid.ms.gov, or requested at 601-359-3984 or by emailing at DOMPolicy@medicaid.ms.gov.

5. Written comments will be received by the Division of Medicaid, Office of the Governor, Office of Policy, Walter Sillers Building, Suite 1000, 550 High Street, Jackson, Mississippi 39201, or DOMPolicy@medicaid.ms.gov for thirty (30) days from the date of publication of this notice. Comments will be available for public review at the above address and on the Division of Medicaid's website at www.medicaid.ms.gov.

6. A public hearing on this SPA will not be held.

State of Mississippi

DESCRIPTIONS OF LIMITATIONS AS TO AMOUNT, DURATION AND SCOPE OF MEDICAL CARE AND SERVICES PROVIDED

The Division of Medicaid covers routine patient costs for items and services furnished in connection with participation in a qualifying clinical trial.

Items and services include any item or service provided to prevent, diagnose, monitor, or treat complications resulting from such participation, to the extent that the provision of such an item or service to the individual outside the course of such participation would otherwise be covered under the State plan or waiver and any item or service required solely for the provision of the investigational item or service that is the subject of such trial, including the administration of such investigational item or service.

The Division of Medicaid does not cover:

1. The item or service that is the subject of the qualifying clinical trial,

2. Not otherwise covered outside of the clinical trial under the State plan or waiver; or

3. An item or service that:

    a) Is provided to the individual solely to satisfy data collection and analysis needs for the qualifying clinical trial, and

    b) Is not used in the direct clinical management of the individual and not otherwise covered under the State plan or waiver.

The term ‘qualifying clinical trial’ means a clinical trial as defined in Section 1905(gg)(2) of the Social Security Act.

State of Mississippi

METHODS AND STANDARDS FOR ESTABLISHING PAYMENT RATES-OTHER TYPES OF CARE

The Division of Medicaid reimburses routine patient costs for items and services furnished in connection with participation in a qualifying clinical trial according to the state plan reimbursement methodology for the item or service provided.

State of Mississippi

DESCRIPTIONS OF LIMITATIONS AS TO AMOUNT, DURATION AND SCOPE OF MEDICAL CARE AND SERVICES PROVIDED

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Items and services include any item or service provided to prevent, diagnose, monitor, or treat complications resulting from such participation, to the extent that the provision of such an item or service to the individual outside the course of such participation would otherwise be covered under the State plan or waiver and any item or service required solely for the provision of the investigational item or service that is the subject of such trial, including the administration of such investigational item or service.

The Division of Medicaid does not cover:

1. The item or service that is the subject of the qualifying clinical trial,

2. Not otherwise covered outside of the clinical trial under the State plan or waiver; or

3. An item or service that:

    a) Is provided to the individual solely to satisfy data collection and analysis needs for the qualifying clinical trial, and

    b) Is not used in the direct clinical management of the individual and not otherwise covered under the State plan or waiver.

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