CABINET FOR HEALTH AND FAMILY SERVICES
Department for Medicaid Services
Division of Fiscal Management
(New Administrative Regulation)

907 KAR 3:190. Reimbursement for treatment related to clinical trials.

RELATES TO: KRS 205.520, 205.5605, 205.5606, 205.5607, 42 U.S.C. 1396d
STATUTORY AUTHORITY: KRS 194A.030(2), 194A.050(1), 205.520(3),
NECESSITY, FUNCTION, AND CONFORMITY: The Cabinet for Health and Family Services, Department for Medicaid Services, has responsibility to administer the Medicaid Program. KRS 205.520(3) authorizes the cabinet, by administrative regulation, to comply with any requirement that may be imposed, or opportunity presented, by federal law to qualify for federal Medicaid funds. 42 U.S.C. 1396d(gg) establishes federal requirements for reimbursement relating to a qualifying clinical trial. In keeping with that federal requirement, this administrative regulation establishes the department's coverage and reimbursement for routine patient costs relating to a qualifying clinical trial.

Section 1. Definitions.
(1) "Department" means the Department for Medicaid Services or its designee.
(2) "Qualifying clinical trial" has the same meaning as in 42 U.S.C. 1396d(gg)(2).
(3) "Routine patient costs" has the same meaning as in 42 U.S.C. 1396d(gg)(1).

Section 2. Policy. Consistent with 42 U.S.C. 1396d(gg), services related to qualifying clinical trials shall be reimbursable if:
(1) The services are covered services pursuant to Title 907 KAR;
(2) The services would otherwise be provided to a participant who is not participating in a clinical trial; and
(3) The services are not covered by the clinical trial sponsor.

Section 3. Qualifying Clinical Trial Treatment Related Expenses.
(1) The department shall comply with 42 U.S.C. 1396d and provide coverage for routine patient costs associated with a qualifying clinical treatment.
(2) Any required coverage determination shall be expedited and completed within seventy-two (72) hours.
(3) In complying with this section, the provider shall not be:
(a) Required to provide the geographic location or network affiliation of a provider associated with a qualifying clinical trial and treating an enrolled Medicaid recipient.
(b) Required to submit:
1. Protocols of the qualifying clinical trial;
2. Proprietary documentation; or
3. Any information determined by the federal Health and Human Services cabinet to be burdensome to provide.
(4)
(a) A provider and principal investigator shall attest to the appropriateness of the qualifying clinical trial by completion of the form located on the Medicaid.gov Web site at this link: https://www.medicaid.gov/resources-for-states/downloads/medicaid-attest-form.docx.
(b) The form established in paragraph (a) shall be submitted upon request and available for auditing purposes.

Section 4. Federal Approval and Federal Financial Participation. The department's coverage and reimbursement of services pursuant to this administrative regulation shall be contingent

upon:

(1) Receipt of federal financial participation for the coverage and reimbursement; and

(2) Centers for Medicare and Medicaid Services' approval of the coverage and reimbursement.

Section 5. Use of Electronic Signatures. The creation, transmission, storage, or other use of electronic signatures and documents shall comply with the requirements established in KRS 369.101 to 369.120.

Section 6. Appeal Rights.

(1) An appeal of a department decision regarding a Medicaid recipient based upon an application of this administrative regulation shall be in accordance with 907 KAR 1:563.

(2) An appeal of a department decision regarding Medicaid eligibility of an individual shall be in accordance with 907 KAR 1:560.

(3) An appeal of a department decision regarding a Medicaid provider based upon an application of this administrative regulation shall be in accordance with 907 KAR 1:671.

(49 Ky.R. 703, 1434; eff. 1-12-2023; 49 Ky.R. 2385; 50 Ky.R. 594; eff. 9-27-2023; 49 Ky.R. 1868; eff. 9-27-2023.)

LISA D. LEE, Commissioner
ERIC C. FRIEDLANDER, Secretary

APPROVED BY AGENCY: February 1, 2023

FILED WITH LRC: February 8, 2023 at 8:05 a.m.

PUBLIC HEARING AND COMMENT PERIOD: A public hearing on this administrative regulation shall, if requested, be held on April 24, 2023, at 9:00 a.m. using the CHFS Office of Legislative and Regulatory Affairs Zoom meeting room. The Zoom invitation will be emailed to each requestor the week prior to the scheduled hearing. Individuals interested in attending this virtual hearing shall notify this agency in writing by April 17, 2023, five (5) workdays prior to the hearing, of their intent to attend. If no notification of intent to attend the hearing is received by that date, the hearing may be canceled. This hearing is open to the public. Any person who attends virtually will be given an opportunity to comment on the proposed administrative regulation. A transcript of the public hearing will not be made unless a written request for a transcript is made. If you do not wish to be heard at the public hearing, you may submit written comments on this proposed administrative regulation until April 30, 2023. Send written notification of intent to attend the public hearing or written comments on the proposed administrative regulation to the contact person. Pursuant to KRS 13A.280(8), copies of the statement of consideration and, if applicable, the amended after comments version of the administrative regulation shall be made available upon request.

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