

May 18, 2023

MB# 23-019

MEDICAID BULLETIN

TO: All Providers

SUBJECT: Medicaid Coverage and Reimbursement of Routine Patient Costs Associated with Qualifying Clinical Trials

The South Carolina Department of Health and Human Services (SCDHHS) has amended the South Carolina State Plan to cover routine patient costs Healthy Connections Medicaid members accrue that are associated with participation in qualifying clinical trials effective Jan. 1, 2022. The agency is making this change consistent with federal guidance outlined in Center for Medicaid and CHIP Services state Medicaid director (SMD) letter [SMD# 21-005](#) and the requirements of the Consolidated Appropriations Act of 2021.

The routine patient costs covered by the Healthy Connections Medicaid program for a Medicaid member participating in a qualifying clinical trial include any item or service provided to the individual under the qualifying clinical trial. This includes any item or service provided to prevent, diagnose, monitor, or treat complications resulting from participation in the qualifying clinical trial. These items or services will be covered for Healthy Connections Medicaid members to the extent they would be covered outside of participation in the qualifying clinical trial under the Medicaid State Plan or waiver, including demonstration projects under section 1115 of the Social Security Act. Some examples of routine costs in a clinical trial could include otherwise covered physician, laboratory or medical imaging services and medically necessary specialist care services (including coverable medically necessary out-of-state costs) arising from clinical trial participation. Information on services affiliated with a qualifying clinical trial have been added to the [Provider Administrative and Billing manual](#).

Routine patient costs do not include any investigational item or service that is the subject of the qualifying clinical trial that is not otherwise covered outside of the clinical trial under the State Plan, waiver, or demonstration project. Routine patient costs also do not include any item or service that is provided to the Medicaid member solely to satisfy data collection and analysis for the qualifying clinical trial that is not used in the direct clinical management of the Medicaid member and is not otherwise covered under the State Plan, waiver, or demonstration project.

A qualifying clinical trial is defined as a clinical trial in any clinical phase of development that is conducted in relation to the prevention, detection, or treatment of any serious or life-threatening disease or condition. To qualify for Medicaid reimbursement, the clinical trial must also be one or more of the following:

- A study or investigation that is approved, conducted, or supported (including by funding through in-kind contributions) by one or more of the following:
 - The National Institutes of Health (NIH);
 - The Centers for Disease Control and Prevention (CDC);
 - The Agency for Health Care Research and Quality (AHRQ);
 - The Centers for Medicare & Medicaid Services (CMS);
 - A cooperative group or center of any of the entities described above or the Department of Defense or the Department of Veterans Affairs; or,
 - A qualified non-governmental research entity identified in the guidelines issued by the NIH for center support grants.

- A clinical trial, approved or funded by any of the following entities, that has been reviewed and approved through a system of peer review and that assures unbiased review of the highest scientific standards by qualified individuals with no interest in the outcome of the review:
 - The Department of Energy;
 - The Department of Veterans Affairs; or,
 - The Department of Defense.

- A clinical trial that is one conducted pursuant to an investigational new drug exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act or an exemption for a biological product undergoing investigation under section 351(a)(3) of the Public Health Service Act.

- A clinical trial that is a drug trial exempt from being required to have one of the exemptions in the prior bullet.

Providers should direct any questions related to this bulletin to the Provider Service Center at (888) 289-0709. The Provider Service Center's hours of operations are 7:30 a.m.-5 p.m. Monday-Thursday and 8:30 a.m.-5 p.m. Friday. Healthy Connections Medicaid members should direct any questions related to this bulletin to the Member Contact Center at (888) 549-0820. The Member Contact Center's hours of operation are from 8 a.m.-6 p.m. Monday-Friday.

South Carolina's Medicaid managed care organizations (MCO) are responsible for the coverage and reimbursement related to routine patient costs for members participating in qualifying clinical trials for Healthy Connections Medicaid members who are enrolled in an MCO.

Thank you for your continued support of the South Carolina Healthy Connections Medicaid program.

/s/

Robert M. Kerr