



Government of the Virgin Islands of the United States

## DEPARTMENT OF HUMAN SERVICES

Medicaid Division

### **MEDICAID PROGRAM PUBLIC NOTICE QUALIFYING CLINICAL TRIALS COVERAGE**

**May 09, 2023**

The Department of Human Services (DHS) is issuing this Public Notice of its intention to establish coverage of routine Medicaid patient costs associated with participation in qualifying clinical trials under the United States Virgin Islands Medicaid Program (USVIMP) effective May 09, 2023.

Division CC, Title II, Section 210 of the Consolidated Appropriations Act, 2021 (Public Law 116-260) (section 210) amended section 1905(a) of the Social Security Act (the Act), by adding to the definition of medical assistance a new benefit at section 1905(a)(30) for routine patient costs for items and services furnished in connection with participation by Medicaid beneficiaries in qualifying clinical trials, subject to further provisions in a new section 1905(gg). 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.

#### **Items and Services Covered Under This Benefit**

Pursuant to section 1905(a)(30) and 1905(gg)(1) of the Act, the routine patient costs that will be covered for a Medicaid beneficiary participating in a qualifying clinical trial are any item or service provided to the individual under the qualifying clinical trial, including any item or service provided to prevent, diagnose, monitor, or treat complications resulting from participation in the qualifying clinical trial, to the extent that the provision of such items or services to the beneficiary would otherwise be covered outside the course of participation in the qualifying clinical trial under the state plan. or waiver, including a demonstration project under section 1115 of the Act.

Such routine services and costs also include any item or service required solely for the provision of the investigational item or service that is the subject of the qualifying clinical trial, including the administration of the investigational item or service. Some examples of routine costs in a clinical trial could include otherwise covered physician services or laboratory or medical imaging services that assist with prevention, diagnosis, monitoring or treatment of complications arising from clinical trial participation.

#### **Items and Services Not Covered Under the New Mandatory Benefit**

As described under section 1905(gg)(1) of the Act, routine patient costs within the meaning of section 1905(a)(30) of the Act do not include any investigational item or service that is the subject of the qualifying clinical trial and is not otherwise covered outside of the clinical trial under the state plan, waiver, or demonstration project.



Government of the Virgin Islands of the United States

## DEPARTMENT OF HUMAN SERVICES

Medicaid Division

Similarly, routine patient cost does not include any item or service that is provided to the beneficiary solely to satisfy data collection and analysis for the qualifying clinical trial that is not used in the direct clinical management of the beneficiary and is not otherwise covered under the state plan, waiver, or demonstration project.

### **Qualifying Clinical Trial**

Section 1905(gg)(2) of the Act defines the term “qualifying clinical trial” for purposes of section 1905(a)(30) of the Act 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 and is described in any of clauses (i)-(iii) of section 1905(gg)(2)(A) of the Act.

### **Reimbursement**

Coverage of the routine patient costs for items and services furnished in connection with participation in qualifying clinical trials pursuant to Section 1905(a)(30) of the Social Security Act will be reimbursed according to the current state plan reimbursement methodology for the item or service provided.

The Medicaid State Plan Amendment which describes this coverage is available for review at:

<http://www.dhs.gov.vi/>

It is also posted for review at the DHS District Offices on St. Thomas, St. Croix, and St. John. You may also call 340-774-0930 on St. Thomas or 340-772-7100 on St. Croix. If you prefer to provide written comments on this proposal, please address them to the following address:

USVI Department of Human Services  
Attn: Director, Medicaid Program  
1303 Hospital Grounds – Building A  
St. Thomas, US Virgin Islands 00802

We invite your comments on the proposal and those comments must be received by DHS within 30 days of the date of this notice.