PAYMENT POLICY ID NUMBER: 10-028

Original Effective Date: 03/25/10

Revised: 05/31/12

Clinical Trials

THIS PAYMENT POLICY IS NOT AN AUTHORIZATION, CERTIFICATION, EXPLANATION OF BENEFITS, OR A GUARANTEE OF PAYMENT, NOR DOES IT SUBSTITUTE FOR OR CONSTITUTE MEDICAL ADVICE. ALL MEDICAL DECISIONS ARE SOLELY THE RESPONSIBILITY OF THE PATIENT AND PHYSICIAN. BENEFITS ARE DETERMINED BY THE GROUP CONTRACT, MEMBER BENEFIT BOOKLET, AND/OR INDIVIDUAL SUBSCRIBER CERTIFICATE IN EFFECT AT THE TIME SERVICES WERE RENDERED. THIS PAYMENT POLICY APPLIES TO ALL LINES OF BUSINESS AND PROVIDERS OF SERVICE. IT DOES NOT ADDRESS ALL POTENTIAL ISSUES RELATED TO PAYMENT FOR SERVICES PROVIDED TO BCBSF MEMBERS AS LEGISLATIVE MANDATES, PROVIDER CONTRACT DOCUMENTS OR THE MEMBER'S BENEFIT COVERAGE MAY SUPERSEDE THIS POLICY.

DESCRIPTION:

Florida Blue understands the importance of cancer clinical trials and is a signatory to the Florida Clinical Trials Agreement.

The intent and purpose of the Florida Clinical Trials Agreement is to provide for insurance coverage for certain services related to cancer for those Floridians covered by the health benefit plans issued by the undersigned health insurers, health maintenance organizations, and self-insured governmental employers. Such coverage will promote the health and welfare of the people of Florida.

There are two general areas covered pursuant to this Agreement: (1) coverage of the routine patient care costs for persons participating in cancer clinical trials within Florida; and (2) coverage of screening tests.

Nothing in the Agreement shall be construed to:

A. Prohibit a health insurer, health maintenance organization, or self-insured governmental employer from restricting coverage for cancer clinical trials to hospitals and physicians in Florida unless the protocol for the cancer clinical trial is not available at a Florida hospital or with a Florida-licensed physician; or
B. Require a health maintenance organization or exclusive provider organization to pay for the services of a non-contracted provider unless payment would otherwise be required under state or federal law, or the subscriber contract.

For more information on the Florida Clinical Trials Agreement, please refer to the references section of this payment policy.

REIMBURSEMENT INFORMATION:

Services provided to a member who is participating in a clinical trial are not reimbursed any different than any other service. If the service is covered under the members benefit plan, the service will be payable.

Furthermore, the Agreement does not require benefit coverage under clinical trials that are otherwise not covered under the health plan for other conditions.

If services are provided by a contracted provider, the payment rate will be at the agreed-upon rate, less applicable insured cost-sharing (e.g. copayments, coinsurance, and/or deductibles).

In the case of a non-participating provider, the payment rate will be determined based on Florida Blue Non-participating Provider Payment Policy.

DEFINITIONS:

CLINICAL TRIAL: A clinical trial is a research study to answer specific questions about vaccines or new therapies or new ways of using known treatments. Clinical trials (also called medical research and research studies) are used to determine whether new drugs or treatments are both safe and effective. Carefully conducted clinical trials are the fastest and safest way to find treatments that work in people. Trials are in four phases: Phase I tests a new drug or treatment in a small group; Phase II expands the study to a larger group of people; Phase III expands the study to an even larger group of people; and Phase IV takes place after the drug or treatment has been licensed and marketed.

PHASE I TRIALS: Initial studies to determine the metabolism and pharmacologic actions of drugs in humans, the side effects associated with increasing doses, and to gain early evidence of effectiveness; may include healthy participants and/or patients.

PHASE II TRIALS: Controlled clinical studies conducted to evaluate the effectiveness of the drug for a particular indication or indications in patients with the disease or condition under study and to determine the common short-term side effects and risks.

PHASE III TRIALS: Expanded controlled and uncontrolled trials after preliminary evidence suggesting effectiveness of the drug has been obtained, and are intended to gather additional information to evaluate the overall benefit-risk relationship of the drug and provide and adequate basis for physician labeling.

PHASE IV TRIALS: Post-marketing studies to delineate additional information including the drug's risks, benefits, and optimal use.

REFERENCES:

Clinical Trial Agreement

COMMITTEE APPROVAL:

This Payment Policy was approved by the Florida Blue Payment Policy Committee on 03/25/10.

GUIDELINE UPDATE INFORMATION:

03/25/10	New Payment Policy.
05/31/12	Revision – Changed name from BCBSF to Florida Blue