blue california
Promise Health Plan

Policy Title: Clinical Trials		POLICY #: 10.2.13 Line of business: Medi-Cal	
Department Name: Utilization Management	**Original Date** 1/02	**Effective Date** 5/19	**Revision Date** 12/18, 3/22, 9/22
Department Head: Sr. Director, UM		**Date: 10/22**	
Medical Services/P&T Committee: (If Applicable) PHP CMO		**Date: 10/22**	

PURPOSE

To establish a process for Blue Shield of California Promise Health Plan (Blue Shield Promise) to cover routine patient care services that are related to the clinical trial for a member diagnosed with cancer and accepted into a phase I, phase II, phase III, or phase IV clinical trial for cancer.

POLICY

Blue Shield Promise will provide coverage for routine patient care costs related to the clinical trial program if the member's treating physician, who is providing covered health care services to the member under the plan, recommends participation in the clinical trial after determining that participation in the clinical trial has a meaningful potential to benefit the member.

Requirements:

1. Member must be diagnosed with cancer and be accepted into Phase I, Phase II, Phase III of Phase IV, Clinical Trial for cancer.
2. The treating physician, who is providing covered health care services to the member under the plan, must recommend participation in the clinical trial.
3. The Clinical Trial Program's endpoints shall be defined to test toxicity as well as to have a therapeutic intent.
4. The treatment shall be provided in a clinical trial that either (1) involves a drug that is exempt under federal regulations from a new drug application or (2) that is approved by one of the following organizations using the most current listing:
    a. One of the National Institutes of Health
    b. The federal Food and Drug Administration, in the form of an investigational new drug application
    c. The United States Department of Defense
    d. The United States Veterans' Administration
5. Blue Shield Promise will only approve coverage for clinical trials to participating hospitals and physicians in Blue Shield Promise provider network unless the protocol for the clinical trial is not provided by a Blue Shield Promise participating provider.
6. Prior Authorization is not required for FDA approved Biomarker testing for members with advanced or metastatic stage 3 or 4 cancer (includes progression/reoccurrence of the above mentioned). Coverage policy for Cancer Biomarker Testing is not limit, prohibit, or modify a member's rights to cancer biomarker testing as part of an approved clinical trial under HSC section 1370.6.

Definitions:
"Routine patient care costs" means the costs associated with health care services that are covered under the plan as well as services that are provided under the approved clinical trial program, including drugs, items, and devices. Followings are the covered services:

1. Health care services typically provided absent a clinical trial
2. Health care services required solely for the provision of the investigational drug, item, device or service.
3. Health care services required for the clinically appropriate monitoring of the investigational item or service.
4. Health care services needed for the reasonable and necessary care arising from the provision of the investigational drug, item, device, or service, including the diagnosis or treatment of the complications.

"Routine patient care costs" do not include the costs associated with any of the following services:

1. Drugs or devices that have not been approved by the federal Food and Drug Administration that are associated with the clinical trial.
2. Services other than health care services, such as travel, housing, companion expenses, and other nonclinical expenses, that a member may require as a result of the treatment being provided for purposes of the clinical trial.
3. Any item or service that is provided solely to satisfy data collection and analysis needs that are not used in the clinical management of the clinical trial.
4. Health care services that, except for the fact that they are being provided in a clinical trial, are otherwise specifically excluded from coverage under the member's health plan.
5. Health care services customarily provided by the research sponsors free of charge for any enrollee in the trial.
6. Experimental treatment outside of an eligible clinical trial.

"Biomarker test" is defined as a diagnostic test, single or multigene, of an individual's biospecimen, such as tissue, blood, or other bodily fluids, for DNA or RNA alterations, including phenotypic characteristics of a malignancy, to identify an individual with a subtype of cancer, in order to guide treatment. Biomarkers, also called tumor markers, are substances found in higher-than-normal levels in the cancer itself, or in blood, urine, or tissues of some individuals with cancer. Biomarkers can determine the likelihood some types of cancer will spread. They can also help doctors choose the best treatment. For some cancers, certain tumor markers may be more helpful for staging than treatment planning.

PROCEDURE

1. Member's treating physician will submit a Treatment Authorization Request (TAR) to Blue Shield Promise Utilization Management (UM) Department for a member participating in a Cancer Clinical Trial for coverage of routine health care services associated with the member's participation in the cancer clinical trial.
2. The Medical Director or physician designee reviews the TAR and makes a determination whether the requests meets all the requirements as listed above. If it meets all requirements, the request is approved. If not approved, both the requesting provider and the member will be notified in writing according to the required timeframes for the determination and notification. (Refer to Policy # 2.0.11, Authorization Denial, Deferral, and/or Modification & Notification)
3. Blue Shield Promise only approves coverage for clinical trial programs to participating hospitals and physicians in Blue Shield Promise provider network unless the protocol for the clinical trial is not provided by a Blue Shield Promise participating provider.

4. Blue Shield Promise provides case management throughout the member's participation in the clinical trial to assist in assuring the member receiving continuity of care and the member has been referred to all available resources for his/her illness.
5. In situation when a member is outside of the plan's service area while participating in a clinical trial, Blue Shield Promise case manager will coordinate non-emergent medically necessary care that is not related to the clinical trial with member's primary care physician or medical group to ensure that non-emergent medically necessary care is covered out of the area.
6. If at any time during the clinical trial, the above requirements for participation in the clinical trial are not met, the member's treatment plan has to be reassessed. If this is reassessment results in a determination of the member's non-eligibility to continue in the clinical trial, appropriate steps are taken in regard to transitioning the routine patient care costs to the appropriate source.
7. The Blue Shield Promise decision to deny or modify experimental or investigation therapies shall be subject to the Independent Medical Review (IMR) process.
8. Upon the Blue Shield Promise decision to deny or modify the service, the member and the requesting provider will be notified in writing of the following:
    a. A statement setting forth the specific medical and scientific reasons for denying the coverage.
    b. A description of alternative treatment, services, or supplies covered by the Plan, if applicable.
    c. Member's right to request an external independent review through the DMHC within five (5) business days of the decision.

REFERENCES

HSC section 1370.6
APL 22-010