Partnership HealthPlan of California
Policy/Procedure

Number: MPUP3086 ***(previously HKUP3086)***	**Lead Department:** Health Services Department
Title: Technology Assessment	
Original Date: *5/21/2008 – Healthy Kids* *10/01/2010 – Healthy Families*	**Reviewed/Revised Date (s): 10/01/10**
Approve/Signature: ☑ **QUAC** ☐ **PAC** ☐ **CRED** ☐ **IQI** ☐ **CEO/Dept. Dir.** ☐ **P & T** *Ronald Chapman, MD, MPH*	**Approval Date: 10/01/2010** *vs. HF*
Applies to: Medi-Cal Partnership*Advantage* ☒ Healthy Kids ☒ Healthy Families	

Attachment:

I. Review of New Medical Technology Form

Purpose: To define the process utilized by PHC to evaluate new technologies including medical and behavioral health procedures, pharmaceuticals and devices as well as changes in the application of existing technologies or adding new benefits for members.

Policy:

I. Definitions: the following definitions apply to entirely new technologies or new applications of existing technologies:

INTERVENTION	Lab or animal studies completed	Human studies completed	FDA or regulatory approval	State Medi-Cal benefit	PHC benefit
Experimental (preclinical trials)	No	No	No	No	No
Investigational (clinical trials in progress)	Yes	No	No	No	If all 6 criteria are met
New technology (clinical trial results available)	Yes	Yes	Yes or No	No	Case-by case review OR Consider addition as a PHC benefit
New benefit	Yes	Yes	Yes	Yes	Yes

II. Investigational interventions:

A. PHC policy for approval of investigational services (interventions) states that all six of the following criteria must be fully met:

1. Conventional therapy will not adequately treat the intended patient's condition;
2. Conventional therapy will not prevent progressive disability or premature death;
3. The provider of the proposed service has a record of safety and success with it equivalent or superior to that of other providers of the investigational service;
4. The investigational service is the lowest cost item or service that meets the patient's medical needs and is less costly than all conventional alternatives;

5. The service is not being performed as part of research study protocol;
6. There is a reasonable expectation that the investigational service will significantly prolong the intended patient's life or will maintain or restore a range of physical and social function suited to the activities of daily living.

B. After collection of all materials necessary to evaluate whether these criteria are met, the PHC Medical Director will review the request. If all criteria are judged to be met, the service will be approved.

C. If all criteria are deemed by the Medical Director not to be met, the case will be referred to a physician reviewer who is a specialist in the area of the intervention to provide an opinion as to whether all of the criteria are met. If so specified by the reviewer, the procedure will be approved.

D. 1. Coverage for Cancer Clinical Trials follows for eligible members who are in any one of the four clinical trial phases as long as the following are met:

The treating physician recommends participation in the trial
Participation in the trial MUST have meaningful potential to benefit the member
The trial must NOT exclusively be to test toxicity, but must have a therapeutic intent
Will NOT occur in the inpatient setting if there is no indication for acute care treatment

2. Trials that qualify for approval include:
   Those involving a drug exempt under federal regulation from a new drug application
   Those approved by the National Institute of Health, The Food and Drug Administration in the form of an investigational new drug application, the United States Department of Defense, or The United States Veterans' Administration

E. May be a qualifying condition under which California Children's Services (CCS) program will provide coverage. Provider of service to refer request to CCS for a determination of coverage and treatment for condition. PHC is not responsible for services authorized by the CCS program- Please refer to MPCP2002 Policy

III. New technologies

A. **Case-by-case review**: if a provider requests approval an intervention categorized as a new technology for an individual member, the following sequence of events will occur:
1. A TAR must be submitted to PHC describing the intervention and containing medical justification for its use, which must include pertinent patient medical records.
2. The medical director will ask the provider for background information, including copies of clinical studies, regarding the intervention. PHC staff also will perform a literature search regarding the use and safety of the intervention, and may in addition use the services of a technology assessment organization such as ECRI or others.

3. The materials collected relating to the request will be forwarded by the medical director to an appropriate specialist (or to an ad-hoc specialist committee) to review the material and to advise PHC regarding the use of the new technology in the case reviewed. The specialist also will be asked to recommend whether the intervention should be considered as a benefit addition for all PHC members.
4. The recommendation of the specialist or specialist committee will be forwarded to the PHC Medical Director for a determination or approval or denial. If a denial determination is made, existing PHC grievance procedures will be followed.
5. The Health Services Department will retain records of all cases so processed, as well as a log of case-by-case new technology benefit determinations.
6. Determination criteria that will be used both by the specialist or committee and the Medical Director will include:
    a. Sufficient objective information regarding the safety, efficacy, and indications for the intervention is available and supports the use of the intervention in this case;
    b. The proposed intervention is likely to lead to a better outcome than conventional interventions that are currently available;
    c. The provider of the proposed service has a record of safety and success with it equivalent or superior to that of other providers of the intervention;
    d. The practitioner who proposes to provide the intervention is willing to accept a payment rate offered by PHC;
    e. The intervention is not being provided as part of a funded research protocol.
7. Evaluation of new and existing medications is done by the process described in the Pharmacy and Therapeutics Committee policy (RP100401.)

B. **Consideration of addition of a new benefit**: A request may be submitted by a provider, a member, or PHC staff that a new technology intervention be added as a PHC benefit. In this case, the following steps will occur:
1. The request should be sent to the medical director and should contain a statement explaining the value of the benefit to PHC members, as well as clinical background information, if available.
2. PHC staff also will perform a literature search regarding the use and safety of the intervention, and may in addition use the services of a technology assessment organization such as ECRI or others.
3. The materials collected relating to the request will be forwarded by the medical director to an appropriate physician (or to an ad-hoc physician committee) to review the material and to advise PHC regarding the use of the new technology. The reviewer or review committee will asked to recommend whether the intervention should be added as a PHC benefit, and if so, to delineate criteria for the use of the new technology.
4. The report of the physician reviewer or review committee is reviewed by PHC staff, and a recommendation formulated by the Internal Quality Improvement Committee. This recommendation is then forwarded to the Quality / Utilization Advisory Committee (Q/UAC) for preliminary approval and then to the Physician Advisory Committee, and if necessary, the Finance Committee, for their consideration. If addition of the new technology intervention is recommended by the PAC, the request will be forwarded to the PHC Commission for their review and final determination.

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IV. Notification of New Benefit Addition:

Once approved by the PHC Commission, information regarding the new benefit will be disseminated in the following manner:

A. All PCPs and appropriate specialists will be notified by mail.

B. PHC Department Heads and Health Services Department staff so that the information can be used in making utilization management determinations, benefit interpretations, care coordination decisions, and designing health educational materials.

C. Notification of the benefit addition will be included in the next Member Newsletter.

DISTRIBUTION

PHC Department Directors, PHC Provider Manual

REVIEW OF NEW MEDICAL TECHNOLOGY FORM

Member Name: _____ **Date:** _____

Member ID# _____ **DOB** _____

Review Type ☐ **Reactive** ☐ **Proactive**

Requesting Practitioner: _____ **Phone #**_____

Proposed Treating Practitioner: _____

Proposed Procedure / Treatment / Medication: _____

_____

_____

Facility: _____ **Phone #** _____

Professional Cost: _____

Anticipated LOS: _____ **Facility Cost:** _____

1. **How long has treating practitioner been performing this procedure or treatment?**

   _____

2. **How many cases has he/she performed?** _____

3. **Estimated Costs:**

Professional	**$**_____
Facility	**$**_____
Other	**$**_____
Total Estimated Cost:	**$**_____

4. **Is privileging or certification required to perform this procedure?**
   ☐ **Yes** ☐ **No**

5. Outcomes Review:

- **Mortality during global period?** _____
- **Mortality during 1 year out?** _____
- **Mortality during 5 years out?** _____
- **Other known complications / risks, actual and anticipated?**

_____

_____

_____

6. Are there other treatment modalities available?

_____

_____

_____

7. Medicare approved? _____

8. FDA approved? _____

9. Hayes Directory review? _____

10. Literature Search? _____

11. Review by Network Practitioners:

Name	**Specialty**
_____	_____
_____	_____
_____	_____
_____	_____

12. Medical Director Review: _____

_____

_____

13. Other comments: _____

_____

_____

14. Send for External Review? Yes_____ No_____

15. Cover? Yes_____ No_____

16. Notify Benefits Coordination? Yes_____ No_____

17. Date Member notification sent _____

18. Date Provider notification sent _____

_____ _____

PHC Medical Director **Date**