PARTNERSHIP HEALTHPLAN OF CALIFORNIA

POLICY / PROCEDURE

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<tr><td colspan="4">Policy/Procedure Number: MCUP3042 (previously UP100342)</td><td colspan="3">Lead Department: Health Services</td></tr>
<tr><td colspan="4">Policy/Procedure Title: Technology Assessment</td><td colspan="3">☒External Policy
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<tr><td>☐ CEO</td><td>☐ COO</td><td colspan="2">☐ CREDENTIALING</td><td colspan="2">☐ DEPT. DIRECTOR/OFFICER</td></tr>
<tr><td colspan="4">Approval Signature: Robert Moore, MD, MPH, MBA</td><td colspan="3">Approval Date: 08/14/2024</td></tr>
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I. RELATED POLICIES:

A. MCUP3041 – Treatment Authorization Request (TAR) Review Process
B. MPRP4001 – Pharmacy and Therapeutics (P&T) Committee
C. MPQP1003 – Physician Advisory Committee (PAC)
D. MPQP1002 – Quality/Utilization Advisory Committee
E. MCUP3138 – External Independent Medical Review

II. IMPACTED DEPTS:

A. Health Services
B. Claims
C. Member Services

III. DEFINITIONS:

A. Biomarker Test: 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.
B. 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	Partnership 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 Partnership benefit
New benefit	Yes	Yes	Yes	Yes	Yes

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IV. ATTACHMENTS:

A. Review of New Medical Technology Form

V. PURPOSE:

To define the process utilized by Partnership HealthPlan of California (Partnership) to evaluate new technologies/investigational services and interventions, 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.

VI. POLICY / PROCEDURE:

A. Investigational Interventions:
   1. Department of Health Care Services (DHCS) policy (Title 22, California Code of Regulations [CCR] Section 51303) for approval of investigational services (interventions) states that all six of the following criteria must be fully met:
      a. Conventional therapy will not adequately treat the intended patient's condition.
      b. Conventional therapy will not prevent progressive disability or premature death.
      c. The provider of the proposed service has a record of safety and success with the investigational service that is equivalent or superior to that of other providers.
      d. 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.
      e. The service is not being performed as part of research study protocol.
      f. There is a reasonable expectation that the investigational service will significantly prolong the intended patient's life and will maintain or restore a range of physical and social function suited to the activities of daily living.
   2. Investigational interventions will not be authorized in the inpatient setting if there is no indication for acute care treatment.
   3. After collection of all materials necessary to evaluate whether these criteria are met, the Chief Medical Officer (CMO) or Physician Designee will review the request. If all criteria are judged to be met, the investigational service will be approved.
   4. If criteria are not met, the case may be sent for independent medical review by a relevant specialist in the area of the intervention. If, in the opinion of the specialist, criteria have been met, the procedure will be approved.

B. Coverage for Cancer Clinical Trials follows Department of Health Care Services (DHCS) guidelines.
   1. Partnership covers routine patient care costs for eligible Members who are in any one of the four clinical trial phases as long as the following are met:
      a. The treating physician recommends participation in the trial
      b. Participation in the trial MUST have meaningful potential to benefit the Member
      c. The trial must NOT exclusively be to test toxicity, but must have a therapeutic intent
      d. Trial will NOT occur in the inpatient setting if there is no indication for acute care treatment
   2. Trials that qualify for approval include:
      a. Those involving a drug exempt under federal regulation from a new drug application OR
      b. The cancer clinical trial is approved by one of the following:
         1) The National Institute of Health
         2) The Food and Drug Administration (FDA) in the form of an investigational new drug application,
         3) The United States Department of Defense
         4) The United States Department of Veterans Affairs
   3. Per Health and Safety Code (HSC) § 1370.6, Partnership does not limit, prohibit, or modify a Member's rights to cancer biomarker testing as part of an approved clinical trial and no prior

authorization is required for either of the following*:

a. Biomarker testing for a Member with advanced or metastatic stage 3 or 4 cancer
b. Biomarker testing for cancer progression or recurrence in a Member with advanced or metastatic stage 3 or 4 cancer

**If the biomarker test is not associated with an FDA-approved cancer therapy for advanced or metastatic stage 3 or 4 cancer, Partnership may still require prior authorization for such testing.*

C. New technologies physician request and authorization process
   1. Case-by-case review: If Partnership receives a physician's request to provide benefits of a new intervention for a specific Member the process is as follows:
      a. A Treatment Authorization Request (TAR) must be submitted to Partnership describing the intervention and containing medical justification for its use. Pertinent patient medical records must be included.
      b. The CMO or Physician Designee will ask the provider for background information including copies of clinical studies regarding the intervention. Partnership staff will perform a literature search for peer reviewed studies or recommendations from professional societies regarding the use, efficacy, and safety of the proposed service. In addition, Partnership will consider determinations of regulatory authorities (e.g. Centers for Medicare and Medicaid Services [CMS] or US Food and Drug Administration [FDA]) concerning the intervention.
      c. The CMO or Physician Designee may request input from a relevant specialist prior to presenting the request to the various committees such as the Pharmacy & Therapeutics (P&T) Committee or Physician Advisory Committee (PAC). This specialist must have expertise in the technology under review.
      d. All behavioral health technologies will include input from an appropriate behavioral health specialist.
      e. When clinically indicated, a case may be sent for external review to a contracted independent medical review organization. (See policy MCUG3138 External Independent Medical Review.)
      f. Based on input from the Utilization Management Department, P&T Committee, PAC or relevant specialist, the CMO or Physician Designee renders a determination.
      g. All records concerning the review are retained by Partnership's Health Services department.
      h. Determination criteria used by the relevant specialist(s), P&T Committee, PAC, and the CMO or Physician Designee must include all six criteria specified in VI.A.1. a. – f. above when reviewers consider the following:
         1) Sufficient objective information regarding the safety, efficacy, and indications for the intervention which support its use.
         2) The proposed intervention is likely to lead to a better outcome than conventional interventions currently available.
         3) The provider has a record of safety and success with the proposed service which is equivalent or superior to that of other providers of the intervention.
         4) The practitioner proposing to provide the intervention is willing to accept the payment rate offered by Partnership.
         5) The intervention is not provided as part of a research study protocol.
      i. Evaluations of new and existing medications are managed by the process described in the Pharmacy & Therapeutics (P&T) Committee policy MPRP4001.

D. Addition of a new benefit:
   1. A request to add a new Partnership benefit may be submitted by a provider, Member or Partnership staff. In such instance the following steps occur:
      a. The request is sent to the CMO or Physician Designee, which includes a statement explaining why the requested service should be added as a Partnership benefit, identification of the Partnership Member to benefit from the service, and all pertinent supporting clinical

information. The Chief Health Services Officer will also review the request and offer feedback.

b. Partnership will perform a literature search regarding the use, efficacy and safety of the intervention and may also use the services of an external technology assessment organization such as ECRI Institute or others. As needed, materials collected relating to the request may be forwarded by the CMO or Physician Designee to an appropriate relevant specialist (or to an ad hoc physician committee) to review the material and to advise Partnership regarding the use of the new technology. The reviewer or review committee is asked to recommend whether the intervention be added as a Partnership benefit and to delineate criteria used to evaluate the use of the new technology. The CMO may also opt to bring the proposal to the Quality/Utilization Advisory Committee (QUAC) or PAC for feedback on the proposal.

c. Partnership also has an operational workgroup for review of potential new benefits called the Benefit Review and Evaluation Workgroup (BREW). BREW is comprised of the Chief Medical Officer, the Chief Health Services Officer, the Chief Operating Officer and representatives from these departments: Regulatory Affairs, Provider Relations, Member Services, Finance, Claims, and Information Technology. BREW investigates and considers the medical, financial and operational issues surrounding proposed benefit changes. BREW findings are summarized and presented to the Partnership Executive Committee which will determine next steps. All medical criteria changes follow the process described in VI.D.1.a. and b. above. The Executive Committee may refer a recommendation to the Board (Partnership Commission) for addition of a new benefit class. The Executive Committee may also request input from the Physician Advisory Committee (PAC) prior to rendering a decision. The Executive Committee may approve coverage of single CPT codes ("minor changes") that it deems are within the general scope of medical services generally covered by Partnership. The Executive Committee will also determine operational changes required such as information technology (IT) and claims configuration and/or financial considerations such as recommending Medi-Cal coverage of new technologies to the California Department of Health Care Services (DHCS).

2. Notification of New Benefit Addition: Once approved by the PAC and the Board (Partnership Commission) as applicable, information regarding the new benefit may be disseminated as necessary in the following manner:
   a. Primary Care Providers (PCPs) and relevant specialists are notified electronically by "Important Provider Notice (IPN)."
   b. Internal notification is sent to Partnership department leadership so that policies and procedures may be created and information gathered to inform utilization management determinations, benefit interpretations, care coordination decisions, and the design of health educational materials.
   c. Partnership Members are notified of benefit additions via the Member Newsletter, updates to the Member Handbook and the Partnership website.

VII. REFERENCES:

A. Title 22, California Code of Regulations (CCR) Section 51303
B. Medi-Cal Provider Manual/ Guidelines: Chemotherapy: An Overview (*chemo an over*)
C. DHCS All Plan Letter (APL) 22-010 Cancer Biomarker Testing (06/22/2022)
D. Health and Safety Code (HSC) § 1370.6
E. National Committee for Quality Assurance (NCQA) Guidelines (Effective July 1, 2024) UM 10 Evaluation of New Technology Elements A & B

VIII. DISTRIBUTION:

A. Partnership Department Directors
B. Partnership Provider Manual
C. Health Services Department Heads and Staff

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IX. POSITION RESPONSIBLE FOR IMPLEMENTING PROCEDURE: Chief Health Services Officer

X. REVISION DATES: 06/21/00; 12/19/01; 10/16/02, 10/20/04; 10/19/05; 10/18/06; 10/17/07; 05/21/08; 07/15/09; 05/18/11; 02/20/13: 01/20/16; 10/19/16; 10/18/17; *06/13/18; 08/14/19; 08/12/20; 08/11/21; 08/10/22; 08/09/23; 08/14/24

*Through 2017, dates reflective of the Quality/Utilization Advisory Committee meeting date. Effective January 2018, Approval Date reflects that of the Physician Advisory Committee's meeting date.

PREVIOUSLY APPLIED TO: N/A

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In accordance with the California Health and Safety Code, Section 1363.5, this policy was developed with involvement from actively practicing health care providers and meets these provisions:

- Consistent with sound clinical principles and processes
- Evaluated and updated at least annually
- If used as the basis of a decision to modify, delay or deny services in a specific case, the criteria will be disclosed to the provider and/or enrollee upon request

The materials provided are guidelines used by Partnership to authorize, modify or deny services for persons with similar illnesses or conditions. Specific care and treatment may vary depending on individual need and the benefits covered under Partnership.

Partnership's authorization requirements comply with the requirements for parity in mental health and substance use disorder benefits in 42 CFR 438.910.