ALAMEDA Alliance FOR HEALTH

Health care you can count on.
Service you can trust.

POLICY AND PROCEDURE

Policy Number	UM-007
Policy Name	New and/or Experimental Technology Review Process
Department Name	Medical Services
Department Chief	Chief Medical Officer
Department Owner	Director Utilization Management
Lines of Business	All
Effective Date	11/21/2006
Subcommittee Name	Quality Improvement Health Equity Committee
Subcommittee Approval Date	TBD
Compliance Committee Approval Date	TBD

POLICY STATEMENT

Alameda Alliance for Health (the Alliance) has an established mechanism for reviewing new and/or experimental technology as well as a new application of existing technology. The Alliance's process for reviewing new and/or experimental technology complies with standards set by Title 42, CFR, §422.202(b).

The intent of the evaluation of new developments in technology and new applications of existing technology is to ensure that Alliance members have equitable access to safe and effective care.

The Alliance reviews new technology and new application of existing technology for inclusion in plan benefits. This review encompasses the following:

- Medical procedures
- Behavioral healthcare procedures
- Pharmaceuticals
- Devices

The Alliance's new technology evaluation process will include:

- The process and decision variables the plan uses to make determinations, including review of:
    - Member access to services
    - Utilization patterns
    - Patient safety
    - Provider consistency in scope of utilization requests
- A review of information from appropriate government regulatory bodies, including the Department of Managed Health Care (DMHC), Department of Health Care Services (DHCS), and the Centers for Medicare and Medicaid Services (CMS).

- A review of information from published scientific evidence.
- Obtaining input from relevant specialists and professionals with expertise in the technology.
- The Alliance's coverage decisions will be based on an assessment of new technology and new applications of existing technology, or on a review of special cases.

PROCEDURE

1. Review and assessment of new and/or experimental technology is the sole responsibility of Alameda Alliance for Health in concert with State and Federal regulatory requirements and is not delegated to any health care partner or Delegated Medical Group. The process is designed to address recognizing and evaluating advances in medical, pharmaceutical, and behavioral health care technologies and includes review of the following:
   i) Medical and Surgical procedures, including transplants
   ii) Drugs and pharmaceuticals
   iii) Behavioral healthcare procedures
   iv) Diagnostic and screening tests
   v) Alternative therapies
   vi) Medical devices/equipment
   vii) Clinical interventions

2. Formal medical policy review (including medical, behavioral health and pharmacy) is conducted once a year using a two-step process requiring input from the Alliance Health Quality Improvement Health Equity Committee (QIHEC). The first step in the process is to propose the technologies and changes to technologies to be evaluated and the second step is the actual revision of existing, or creation of new, policies. The QIHEC is the approving body in both steps. Special case reviews are conducted throughout the year and are approved by the CMO in accordance with review processes and timelines. The information from those special case reviews is used as input into the routine, formal process. The information from both processes is used for benefit determinations and coverage decisions.

3. In preparing for the policy review, the UM Medical Director will coordinate the collection of necessary information about new and/or experimental technology and new uses of existing technology for review by the CMO, who will then propose to the QIHEC the subject areas to be evaluated:

   The CMO will obtain input from the (QIHEC) and the Pharmacy and Therapeutics Committee (P&T) for specific subjects and recommendations for review of new and/or experimental technology that should be considered for benefit coverage policy development.

4. The UM Medical Director will provide the proposed list of services and technologies to the CMO along with a summary and rationale for why the services should be evaluated. The CMO will present the list to the QIHEC for discussion and approval.

5. Once the QIHEC approves the list of subject areas, the Alliance UM Medical Director, Pharmacy Director, or Behavioral Health (BH) Director will develop coverage policies that support decisions about use of new technology and new application of existing technology.
   a. The UM Medical Director, with Medical Management Department staff (including pharmacy and behavioral health staff where relevant), will review all

relevant research on the service, technology, or procedure, from available resources.

6. The Alliance uses appropriate industry resources to develop unbiased, evidenced-based assessments of the safety and efficacy of new, emerging, and controversial health technologies and evaluation of the impact of these technologies on healthcare quality, utilization, and cost.

7. The CMO, and the appropriate Medical Directors will identify benefit topics for which coverage policy development is indicated, i.e. sufficient benefit guidance/criteria for new or experimental technology are lacking.

8. The UM Medical Director, Pharmacy Director and BH Director will develop an initial assessment for specific each new or experimental technology topic consisting of an evaluation of scientific evidence to form conclusions about the benefits/risks of a particular device, therapy, procedure, diagnostic test, or preventive strategy in relation to its potential clinical use for a defined group of individuals.

9. The CMO reviews the draft coverage policies that are developed and presents the review of new and/or experimental technology research findings to the QIHEC (and P&T for applicable pharmaceutical technology) for discussion and decision.

10. The UM Medical Directors will draft the Coverage Policy Statement for CMO review and approval.

11. Following CMO approval, each Coverage Policy Statement will be:
    i) Made available to providers through:

        (1) Announcement of policy publication and availability in the next scheduled Provider Bulletin
            (a) Contacting the UM Department at to request policy copies
            (b) Posting on Alliance website Provider Portal (when feature is available).

Delegation Oversight

The Alliance adheres to applicable contractual and regulatory requirements and accreditation standards**.** All delegated entities with delegated utilization management responsibilities will also need to comply with the same standards. Refer to CMP-019 Delegation Oversight.

DEFINITIONS

Experimental Service: According to Title 22, CCR, Section 51056.1, an experimental service is any drug, equipment, procedure, or service that is in the testing phase undergoing laboratory and/or animal studies prior to testing in humans.

Investigational Service: According to Title 22, CCR, Section 51056.1, an investigational service is any drug, equipment, procedure, or service for which laboratory and/or animal studies have been completed and for which human studies are in progress but:

a. Testing is not complete; and

b. The efficacy and safety of such services in human subjects is not yet established; and

c. The service is not in wide usage.

Technology Assessment - A process established to evaluate the appropriate use of new technologies, new applications of existing technologies and the organizational or supportive systems within which such care is delivered. Services, procedures, pharmacological treatments, and behavioral health procedures are reviewed.

AFFECTED DEPARTMENTS/PARTIES

All Alliance Departments

RELATED POLICIES AND PROCEDURES AND OTHER RELATED DOCUMENTS

CMP-019 Delegation Oversight

RELATED WORKFLOW DOCUMENTS OR OTHER ATTACHMENTS

None

REVISION HISTORY

1/1/2008, 10/28/2009, 6/12/2012, 4/25/2014, 01/10/2016, 12/15/2016, 04/16/2019, 5/21/2020, 5/20/2021, 6/28/2022,6/20/2023, 04/24/2024

REFERENCES

NCQA UM 10 Evaluation of New Technology
Title 42, CFR, Section 422.202(b)

MONITORING

The Compliance and Utilization Department will review this policy annually for compliance with regulatory and contractual requirements. All policies will be brought to the Healthcare Quality Committee annually.