	<b>POLICIES AND PROCEDURES</b>
<b>Policy #:</b> 404-1714	<b>Lead Department:</b> Utilization Management
<b>Title:</b> Technology Assessment	
<b>Original Date:</b> 12/01/2006	<b>Date Published:</b> 01/22/2025
<b>Approved by:</b> Utilization Management Work Group (UMWG)	

**Purpose:**

To define the process that Central California Alliance for Health (the Alliance) uses to evaluate new and emerging technologies and new uses for existing technologies such as medical and mental health procedures, pharmaceuticals, and devices and to determine whether a new technology should be added as a benefit.

**Policy:**

Alliance policy follows Title 22 regulations as defined below:


§ 51056.1. Experimental Services

1. Experimental services are not covered.
2. Investigational services are not covered except when it is clearly documented that all of the following apply:
  - 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 equivalent or superior to that of other providers of the investigational service;
  - 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 specific service (investigational drug, device or procedure) is not being performed as part of a research study protocol (i.e. the specific service, drug device or procedure is covered by the study sponsor)

Alliance policy follows Title 10 regulations as defined below:

§ 2699.6700. Scope of Health Benefits

Clinical Trial for Cancer Patients: Coverage for a subscriber's participation in a clinical trial when the subscriber has been diagnosed with cancer and has been accepted into a phase I through phase IV clinical trial for cancer, and the subscriber's treating physician recommends participation

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in the clinical trial after determining that participation will have a meaningful potential to benefit the subscriber.


Coverage includes the payment of costs associated with the provision of routine patient care, including drugs, items, devices and services that would otherwise be covered if they were not provided in connection with an approved clinical trial program; services required for the provision of the investigational drug, item, device or service; services required for the clinically appropriate monitoring of the investigational drug, item, device, or service; services provided for the prevention of complications arising from the provision of the investigational drug, item, device, or service; and services needed for the reasonable and necessary care arising from the provision of the investigational drug, item, device, or service, including diagnosis or treatment of complications.

Exclusions: Provisions of non-FDA-approved drugs or devices that are the subject of the trial; services other than health care services, such as travel, housing, and other non-clinical expenses that a member may incur due to participation in the trial; any item or service that is provided solely to satisfy data collection and analysis needs and that is not used in the clinical management of the patient; services that are otherwise not a benefit (other than those excluded on the basis that they are investigational or experimental); and services that are customarily provided by the research sponsors free of charge for any enrollee in the trial. Coverage for clinical trials may be restricted to participating hospitals and physicians in California, unless the protocol for the trial is not provided in California.

#### **Definitions:**

##### **Title 22, § 51056.1. Experimental Services**


1. Experimental services means those drugs, equipment, procedures or services that are in a testing phase undergoing laboratory and/or animal studies prior to testing in humans.
2. Investigational services means those drugs, equipment, procedures or services for which laboratory and 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 are not yet established; and

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- c. The service is not in wide usage.
3. The determination that a service is experimental or investigational is based on:
- Reference to relevant federal regulations, such as those contained in Title 42, Code of Federal Regulations, Chapter IV (Health Care Financing Administration) and Title 21, Code of Federal Regulations, Chapter I (Food and Drug Administration);
- a. Consultation with provider organizations, academic and professional specialists pertinent to the specific service;
  - b. Reference to current medical literature.

**Procedures:**


- 1. Coverage for Investigational Services
- 2. After collection of all materials necessary to evaluate whether these criteria are met, an Alliance Medical Director will review the request.
  - a. If all criteria are judged to be met, the service will be approved.
  - b. If all criteria are deemed by the Medical Director not to be met, a consultation may be obtained from a physician who is a specialist in the area of the intervention or referred to an External Independent Review Organization (EIRO) for medical review by a specialist in the area of the intervention to provide a determination as to whether all of the criteria are met.
  - c. If the physician reviewer believes that the case meets all six criteria outlined in policy provisions #2 (a) through (e) above, the procedure will be approved.
  - d. Whenever possible, the Alliance will use contracted physicians and contracted facilities when investigational procedures are authorized.
- 3. Coverage for Cancer Clinical Trials
  - a. The Alliance 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:
    - i. The treating physician recommends participation in the trial;

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- ii. Participation in the trial MUST have meaningful potential to benefit the member;
- iii. The trial must NOT exclusively be to test toxicity, but must have a therapeutic intent; and
- iv. The trial must NOT occur in the inpatient setting if there is no indication for an inpatient hospital stay.
- v. Effective 01/01/2022, pharmacy services billed as pharmacy claims are carved out to fee-for-service under Medi-Cal Rx. Medi-Cal Rx is responsible for formulary management, prior authorization, and claims processing.

Current pharmacy policy embodied in CCS Numbered Letters will be integrated into Medi-Cal Rx policy to ensure continuity of services to support the WCM program. Authorized Prescription Drugs CCS-eligible members transitioning into the Alliance are allowed continued use of any currently physician administered (PAD) drug that is prescribed part of their therapy for the CCS-eligible condition. The CCS-eligible member must be allowed to use the prescribed drug until the Alliance and the prescribing physician agree that the particular drug is no longer medically necessary or is no longer prescribed by the county CCS program provider.

- b. Trials that qualify for approval include:
  - i. Those involving a drug exempt under federal regulation from a new drug application.
  - ii. 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.
- c. When available and possible, the Alliance will use contracted physicians and facilities to provide these services.


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4. Coverage for Pediatric Acute-Onset Neuropsychiatric Syndrome (PANS) and Pediatric Autoimmune Neuropsychiatric Disorders Associated with Streptococcus (PANDAS)


Case-by-case review: Coverage for PANS and PANDAS shall adhere to the treatment recommendations delineated in current clinical practice guidelines published in peer-reviewed medical literature or put forth by organizations composed of expert treating clinicians.

5. New Technologies

- a. Case-by-case review: if a provider requests approval for an intervention categorized as a new technology for an individual member, the following sequence of events will occur:
  - i. An Authorization Request must be submitted to the Alliance describing the intervention and containing medical justification for its use, along with pertinent patient medical records.
  - ii. The Alliance will ask the provider for supporting medical documentation, including copies of clinical studies regarding the intervention. Alliance staff will perform a medical literature search regarding the use and safety of the intervention, research benchmark plans, and may use the services of an EIRO or technology assessment organization as needed.
  - iii. The supporting medical documentation will be forwarded to the Medical Director. Supporting documentation should provide evidence that:
    1. Sufficient objective information regarding the safety, efficacy, and indications for the intervention is available and supports the use of the intervention in this case;
    2. The proposed intervention is likely to lead to a better outcome than a conventional intervention that is currently available;
    3. The provider of the proposed service has a record of safety and success with it equivalent or superior to that of the other providers of the intervention;

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4. The intervention is not being provided as part of a funded research protocol;
5. In cases where safety and efficacy of an intervention are equivalent to conventional therapies, cost-effectiveness will be taken into consideration.
- iv. The Medical Director may consult with contracted specialists or tertiary care physicians in making this determination. If a denial determination is made, existing Alliance grievance procedures will be followed.
- v. The Alliance Medical Director will also consider whether this new technology should be considered as a new benefit for all Alliance members.
6. Consideration of adding a new benefit:
  - a. A request may be submitted by a provider, a member, or Alliance staff that a new technology intervention or device be added as an Alliance benefit. In this case, the following steps will occur:
    - i. The request should be sent to the Medical Director and should contain a statement explaining the value of the benefit to Alliance members, as well as clinical background information, if available.
    - ii. Alliance Utilization Management, and/or Pharmacy staff members will determine if there are existing clinical criteria in MCG care guidelines and/or information from appropriate government regulatory bodies (FDA, DHCS, DMHC). Alliance staff also will perform a literature search for scientific information regarding the use and safety of the intervention, research benchmark plans, and may use the services of an EIRO or technology assessment organization.
    - iii. The materials collected relating to the request will be forwarded to the Medical Director for review.
    - iv. The Medical Director will bring their recommendations to the Utilization Management Work Group (UMWG), consisting of health services clinicians from UM, CM, ECM, BH, Pharmacy, QI and MDs, for discussion

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and review. If approved by the UMWG, this request will be referred first to the Benefits Hub and will continue in the Hub process to determine whether this new technology intervention or device should become a benefit as well as address any Claims, Finance, Member Services, and Provider Services issues. Relevant specialists within the UMWG will review the new technologies requests and will elicit specialist input from EIRO, as needed.

- v. Behavioral Health will be considered as a new benefit.
  - 1. The Alliance contracts with a Managed Behavioral Health Organization (MBHO), Carelon, to provide non-specialty mental health services from licensed mental health care providers for Medi-Cal members through June 30, 2025. Severe conditions requiring Specialty Mental Health Services will be referred to the local County Mental Health Plan (MHP). Carelon is delegated to conduct technology assessments for behavioral health procedures through contract termination. Beginning July 1, 2025, the Alliance will manage technology assessments in-house through its core organizational functions.
- vi. The Alliance's technology assessment process includes device evaluation


b. Notification of New Benefit Addition:

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

- i. All primary care providers (PCPs) and appropriate specialists will be notified as required by contract or law.
- ii. Alliance department heads and Health Services Department staff will be notified of this change.
- iii. All members will be notified of the new benefit as required by Alliance processes.

**References:**

Alliance Policies:

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200-9002 –Member Grievance and appeal System  
 403-1109 – Non-FDA Approved Drugs and Herbal Remedies  
 404-1113 – External Independent Medical Review  
 Impacted Departments:  
     Claims  
     Finance  
     Member Services  
     Pharmacy  
     Provider Services  
 Regulatory:  
     Title 22 CCR Sections 51056.1(b), 51056.1(c) and 51303(h)  
 Legislative:  
     AB 2105: Coverage for PANDAS and PANS  
 Contractual (Previous Contract):  
     DHCS Medi-Cal Contract, Exhibit A, Attachment 10, Provision 9  
 Contractual (2024 Contract):  
     Medi-Cal Contract, Exhibit A, Attachment 3, Provision 5.3.8  
 DHCS All Plan Letter:  
     APL 23-034 – California Children’s Services Whole Child Model Program  
     APL 22-012 – Medi-Cal Pharmacy Benefit to Medi-Cal RX  
 NCQA (Effective 04/08/2024):  
     NCQA UM 10A/B  
 Supersedes:  
     APL 18-023 and 21-005 – California Children’s Services Whole Child Model Program is superseded by 23-034  
     APL 20-020 – Medi-Cal Pharmacy Benefit to Medi-Cal RX is superseded by 22-012  
 Other References:  
 Attachments:

**Lines of Business This Policy Applies To**

- ☐ DSNP  
☒ Medi-Cal  
☒ Alliance Care IHSS


**LOB Effective Dates**

(01/01/2026 – present)  
 (01/01/1996 – present)  
 (07/01/2005 – present)

**Revision History:**

Reviewed Date	Revised Date	Changes Made By	Approved By
12/09/2020	12/09/2020	Tammy Brass, RN, UM/CCM Manager	UMWG



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Reviewed Date	Revised Date	Changes Made By	Approved By
10/19/2021		Kat Reddell, Compliance Specialist II	<i>Medi-Cal Rx</i>
7/27/2023	7/27/2023	Carissa Grepo, RN UM Manager – Prior Auth	UMWG
04/08/2024	04/08/2024	Carissa Grepo, RN UM Manager – Prior Auth	UMWG
12/10/2024	12/27/2024	Kelly Tlemcani, Business Analyst II	UMWG