	POLICIES AND PROCEDURES
Policy #: 404-1112	Lead Department: Utilization Management
Title: Medical Necessity- The Definition and Application of Medical Necessity Provision to Authorization Requests	
Original Date: 06/01/2003	Date Published: 12/05/2024
Approved by: Utilization Management Work Group (UMWG)	

Purpose:

To define medical necessity and to describe how Central California Alliance for Health (the Alliance) applies medical necessity criteria in making utilization management (UM) decisions.

Policy:

The Alliance utilization process provides a system that ensures equitable access to appropriate, cost-effective health care resources for all members. For authorization purposes, a requested service or medical equipment is approved if it is a covered benefit and is determined to be medically necessary. Policies, processes, strategies, evidentiary standards, and other factors used for UM decisions are consistently applied to medical/surgical, mental health, and substance use disorder services and benefits. This policy will define how the utilization management process applies the “medical necessity” provision to authorization requests.

Definitions:


California Children’s Services (CCS): CCS is a state program for children with certain diseases or health problems. Through this program, children up to 21 years of age can get the health care and services they need for CCS-eligible conditions. CCS also provides medical therapy services that are delivered at public schools through their Medical Therapy Unit (MTU).

California Children Services (CCS) Provider: Means any of the following Providers when used to treat Members for a CCS condition:

- A. A medical Provider that is paneled by the CCS program, pursuant to Health and Safety Code, Article 5 (commencing with Section 123800) of Chapter 3 of Part 2 of Division 106.
- B. A licensed acute care hospital approved by the CCS program.
- C. A special care center approved by the CCS program.

Covered Services: Medical Case Management and those services set forth in Title 22, California Code of Regulations (CCR), Division 3, Subdivision 1, beginning with Section 51301; and Title 17, CCR, Chapter 4, Subchapter 13, Article 4, beginning with Section 6840; excluding services listed in the State Medi-Cal contract. Covered Services shall include case management, and Targeted Case Management (TCM) services.

Early and Periodic Screening, Diagnostic, and Treatment (EPSDT): A comprehensive and preventive child program for individuals under the age of twenty-one (21) years. EPSDT is defined by law in the Federal Omnibus Budget Reconciliation Act of 1989 and includes periodic screening, vision, dental and hearing services. EPSDT services are extra Medi-Cal services. This program helps find and care for health problems in children from birth to 21 years of age.

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Members who are under the age of 21, to the extent they are eligible for services through the Medicaid Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) benefit, regardless of the level of distress or impairment, or the presence of a diagnosis; Pursuant to WIC Section 14059.5(b)(1), for individuals under 21 years of age, a service is considered “Medically Necessary” or a “Medical Necessity” if the service meets the standards set forth in federal Medicaid law for EPSDT (Title 42 of the USC Section 1396d(r)(5)). Therefore an EPSDT Covered Service is considered Medically Necessary or a Medical Necessity when it is necessary to correct or ameliorate defects and physical and mental illnesses and condition, regardless of how the condition is discovered.

For members under the age of 21, The Alliance does not impose limits on EPSDT services. Services that are “Medically Necessary” or a “Medical Necessity” in accordance with the standards set forth in Section 1396d(r)(5) of Title 42 of the United States Code (U.S.C.), which also includes NSMHS, are covered by the Alliance as EPSDT services; and Members of any age with potential mental health disorders not yet diagnosed.

Medical Necessity decisions are individualized. Flat or hard limits based on a monetary cap or budgetary restraints are not consistent with EPSDT requirements or Alliance review processes. . When Medically Necessary, the Alliance does not impose limits on EPSDT services and covers services listed in Section 1905(a) of the SSA regardless of whether or not they have been approved under a State Plan Amendment (SPA).

The Alliance uses the current AAP/Bright Futures periodicity schedule and guidelines when delivering care to any Member under the age of 21, including but not to health and developmental screening services, physical examination, dental services, vision services, and hearing services. All Members under the age of 21 must receive EPSDT preventive services, including screenings, designed to identify health and developmental issues as early as possible. The Alliance works to ensure Members under the age of 21 have timely access to all Medically Necessary services and that appropriate diagnostic and treatment services are initiated as soon as possible, but no later than 60 calendar days following either a preventive screening or other visit that identifies a need for follow-up. The Alliance is the primary provider of such medical services except for those services that have been expressly carved-out. Please see Alliance policies 200-2000 New Member Materials and 405-1306 Community Care Coordination Services for further details on EPSDT services.

Generally Accepted Standards of Mental Health and Substance Use Disorder Care: Standards of care and clinical practice that are generally recognized by health care providers practicing in relevant clinical specialties such as psychiatry, psychology, clinical sociology, addiction medicine and counseling, and behavioral health treatment pursuant to Section 1374.73 (CCR, T28). Valid, evidence-based sources establishing generally accepted standards of mental health and substance use disorder care include peer-

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reviewed scientific studies and medical literature, clinical practice guidelines, specialty societies and federal government agencies, and drug labeling approved by the United States Food and Drug Administration. In addition to recommendations and criteria from nonprofit professional associations in accordance with CCR Title 28 § 1300.74.721 for the Alliance Care IHSS line of business (LOB).

Medically Necessary or Medical Necessity: When applied to Members 21 years of age or older will include all Covered Services that are reasonable and necessary services to protect life, to prevent significant illness or significant disability, or to alleviate severe pain through the diagnosis or treatment of disease, illness or injury. Medically Necessary services shall include Covered Services necessary to achieve age-appropriate growth and development, and attain, maintain, or regain functional capacity.


For purposes of this section, “medically necessary treatment of a mental health or substance use disorder” means a service or product addressing the specific needs of that patient, for the purpose of preventing, diagnosing, or treating an illness, injury, condition, or its symptoms, including minimizing the progression of that illness, injury, condition, or its symptoms, in a manner that is all of the following:

- (i) In accordance with the generally accepted standards of mental health and substance use disorder care.
- (ii) Clinically appropriate in terms of type, frequency, extent, site, and duration.
- (iii) Not primarily for the economic benefit of the health care service plan and subscribers or for the convenience of the patient, treating physician, or other health care provider.

Whole Child Model (WCM): The purpose of the WCM program is to incorporate services covered by the CCS Program into Medi-Cal managed care for Medi-Cal-eligible CCS Program members. Managed care plans (MCPs) operating in WCM counties will integrate Medi-Cal managed care and CCS Program administrative functions to provide comprehensive treatment of the whole child and care coordination in the areas of primary, specialty, and behavioral health for CCS-eligible and non-CCS-eligible conditions.

The following definition of Medical Necessity is for use with Alliance **Medi-Cal line of business (LOB):** Services or equipment are deemed medically necessary when an intervention is recommended by the treating health care provider and determined by the Alliance’s medical director, licensed pharmacist, or designated licensed RN or LVN to be all of the following:

1. For the purpose of treating a medical condition and meeting criteria set forth in Title 22, Article 4, Section 51303: “Health care services, which are reasonable and necessary to protect life, to prevent significant illness or significant disability, or to alleviate severe pain through the diagnosis or treatment of disease, illness or injury;”
2. For individuals under 21 years of age, a service is Medically Necessary or a “medical necessity” if it is necessary to correct or ameliorate defects and physical and mental illnesses or

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- conditions, including behavioral health conditions discovered by a screening service, under the Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) standard set forth in 42 of the USC Section 1396d(r)(5), as required by W&I Code Sections 14059.5(b)(1) and 14132(v), and as described in DHCS APL 23-005, regardless of whether those services are covered in the state's Medicaid State Plan. The Alliance shall determine Medical Necessity on a case-by-case basis, taking into account the individual needs of the child.
3. The most clinically appropriate item or level of service in accordance with generally accepted standards of medical practice in terms of type, frequency, extent and duration, considering potential benefits and harms to the patient;
 4. Treatment is known to be effective in improving health outcomes and in accordance with generally accepted standards of medical practice for the illness, injury or disease;
 5. Not primarily for the convenience of the member or health care provider.


In addition, there are several references to the definition of "Medical Necessity" that are applicable to the Alliance process of making covered service determinations. The references relate to both regulatory and accreditation requirements and are:

1. **Department of Health Care Services (DHCS) Alliance Contract:** Medically Necessary or Medical Necessity means reasonable and necessary Covered Services to protect life, to prevent significant illness or significant disability, or alleviate severe pain through the diagnosis or treatment of disease, illness, or injury, as required under W&I Code 14059.5(a) and 22 CCR Section 51303(a). Medically Necessary services shall include Covered Services necessary to achieve age- appropriate growth and development, and attain, maintain, or regain functional capacity.

For Members under 21 years of age, a treatment or service is Medically Necessary if it is necessary to correct or ameliorate defects and physical and mental illnesses or conditions under the Early and Periodic Screening, Diagnostic and Treatment (EPSDT) standard set forth in 42 USC Section 1396d(r)(5), as required by W&I Code Sections 14059.5(b)(1) and 14132(v), and as described in APL 23-005.

The Alliance shall determine Medical Necessity on a case-by-case basis, taking into account the individual needs of the child.

2. According to the **Alliance Medi-Cal Evidence of Coverage (EOC) Definition**, medically necessary is defined as: "Reasonable and necessary types of service to protect life; keep the patient from getting seriously ill or disabled; or reduce severe pain through the diagnosis or treatment of disease, illness or injury."
3. **Department of Managed Health Care (DMHC):** The determination that an intervention recommended by a treating practitioner is (1) the most appropriate available supply or level of service for the individual in question, considering potential benefits and harms to the


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individual, and (2) known to be effective in improving health outcomes. For interventions not yet in widespread use, a plan determines effectiveness, based on the best available scientific evidence. For established interventions, a plan determines effectiveness based on scientific evidence, professional standards and expert opinion.

The Alliance currently contracts with a Managed Behavior Health Organization (MBHO) for the provision of mental health and/or substance use disorder services. The Alliance requires the MBHO to utilize a definition of medical necessity that is consistent with, and no more restrictive than, the Alliance's Knox-Keene licensed LOBs definition of medical necessity when making determinations for members in any of the Plan's Knox Keene licensed LOBs. This requirement will remain in place until contract expiration on June 30, 2025. Beginning July 1, 2025, the Alliance will ensure through its core organizational functions, that it applies the least restrictive definition of medical necessity.

Decision Hierarchy:

1. Title 22 criteria, [etc.] for Medi-Cal LOB medical necessity determinations
2. Knox Keene Act and Title 28 criteria, [etc.] for Knox Keene licensed LOB medical necessity determinations
3. Medi-Cal Medical Necessity Guidelines (when available and applicable)
4. Alliance policies, including: UM policies approved by the UMWG and Quality Improvement and Health Equity Committee (QIHEC); and Pharmacy policies approved by the Pharmacy and Therapeutics Committee
5. Evidence-based guidelines, such as
 - a. MCG care guidelines
 - b. Medicare (CMS) Guidelines
 - c. Criteria and guidelines set forth in the most recent versions of treatment criteria developed by the nonprofit professional association for the relevant clinical specialty
 - d. World Professional Association for Transgender Health (WPATH) guidelines, SOC 8 (Standard of Care, Version 8 or most updated version)
6. Consensus statements and nationally recognized standards of practice.
7. Guidelines developed by other health plans
8. Expert opinion:
 - a. Clinical advisors serving on Alliance Committees
 - b. Outside Independent Medical Review
9. For WCM CCS-eligible members:
 - a. Use all current and applicable CCS program guidelines, including CCS program regulations, CCS numbered letters, and CCS program information notices in

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developing criteria for use by the plan's chief medical officer or the equivalent and other care management staff for the member's CCS eligible condition.

- b. In cases in which applicable CCS clinical guidelines do not exist, use evidence-based guidelines or treatment protocols that are medically appropriate given the member's CCS-eligible condition.

All clinical practice guidelines must meet the following criteria:


1. Are based on valid and reliable clinical evidence or a consensus of health care professionals in the relevant field;
2. Consider the needs of Members;
3. Stem from recognized organizations that develop or promulgate evidence-based clinical practice guidelines, or are developed with involvement of board-certified providers from appropriate specialties;
4. Have been reviewed by the Alliance's medical director, as well as subcontractors, downstream subcontractors, and network providers, as appropriate;
5. Reviewed routinely with non-staff network practitioners at QIHEC; and,
6. Are reviewed and updated annually.

The Alliance's processes to adopt, disseminate, and monitor the use of clinical practice guidelines are further described in Alliance Policy 404-1101 – Utilization Management Program.

Members can access criteria via the Member Handbook, the Alliance website and upon request by calling Member Services at 800-700-3874 ext. 5505. For the Hearing or Speech Assistance Line, members may call 800-735-2929 (TTY: Dial 711).

Procedures:


1. The Alliance ensures the provision of all Medically Necessary Covered Services, including services which exceed the services provided by Local Education Agencies (LEA), Regional Centers, or local governmental health programs.
2. The Alliance shall ensure that services provided are sufficient in amount, duration, or scope to reasonably achieve the purpose for which the Covered Services are furnished and may not arbitrarily deny or reduce the amount, duration, or scope of a required service solely because of the diagnosis, type of illness, or condition. Services supporting Members with ongoing or chronic conditions, or who require Managed Long-Term Services & Supports (MLTSS), are provided in a manner that reflects the Member's ongoing needs.

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3. For medical authorization purposes, a requested item/service will be approved if it is a Covered Service, and it is Medically Necessary.

4. For Medi-Cal members under the age of 21, the Alliance will provide, cover, and arrange for all medically necessary EPSDT services identified at a preventative screening or other visit indicating the need for diagnosis or treatment, either directly or through referral to appropriate agencies, organizations, or individuals, which include any services set forth in 42 USC Section 1396d(a), when the services are determined to be medically necessary to correct or ameliorate physical and/or mental health conditions, regardless of whether such services are covered under the State Plan.
 - a. A service need not cure a condition in order to be covered under EPSDT. Services that maintain or improve the child's current health condition, or those that can prevent adverse health outcomes, are also covered under EPSDT because they "ameliorate" a condition.
 - b. Maintenance services are defined as services that sustain or support rather than those that cure or improve health problems. Services are covered when they prevent a condition from worsening or prevent development of additional health problems. The common definition of "ameliorate" is to "make more tolerable or to make better."
 - c. EPSDT members are referred for coordination of care and review for TCM services. If Members under age 21 are not eligible for or accepted for Medically Necessary TCM services by a Regional Center or local government health program, The Alliance shall ensure the Members' access to comparable services under the EPSDT benefit in accordance with APL 23-005.
 - d. Consistent with federal guidance from CMS, behavioral health services, including NSMHS, need not be curative or completely restorative to ameliorate a behavioral health condition. Services that sustain, support, improve, or make more tolerable a behavioral health condition are considered to ameliorate the condition and are this medically necessary and are covered as EPSDT services.¹
 - i. The Alliance will ensure that any Managed Behavior Health Organization (MBHO) subcontracted with the Alliance for the provision of mental health and/or substance use disorder services utilizes a definition of medical necessity that is consistent with this definition through contract expiration on June 30, 2025.

5. Documentation required for review to support the Medical Necessity of a provider's requested items/services may include, but is not limited, to:

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- a. A completed authorization request or authorized referral request,
 - b. Any/all clinical documentation needed to fulfill Alliance policy/criteria requirements for establishing/meeting Medical Necessity.
6. Medical necessity review considers the coverage of items/services as appropriate within the member's benefit structure.
 7. Specific to Alliance Care IHSS LOB and in accordance with APL 24-007, if an enrollee meets the criteria for a specific level of care as determined by the applicable medical necessity assessment, but clinical services or supports for that level are available, then the next higher level of care is authorized.
 8. Following review of the submitted clinical documentation, Alliance staff make determinations for coverage of Medically Necessary items/services by applying written criteria based on sound clinical evidence.
 9. Decisions regarding Medical Necessity are applied in accordance with: industry standards; nationally recognized guidelines and resources such as MCG care guidelines that are objective and evidence-based criteria; generally accepted standards of medical practice and expert clinical opinion. The Alliance considers individual circumstances (age, co-morbidities, complications, progress of treatment) and the local delivery system such as availability of specialists and requested services when making these decisions.
 10. An intervention may be Medically Necessary, yet not be a covered benefit.
 11. Decisions regarding medical items or services that are considered investigational/experimental will be guided by Alliance Policy 404-1714 - Technology Assessment as indicated.
 12. When MCG and/or CMS is not appropriate for an individual or delivery system needs, the Alliance defaults to the decision hierarchy delineated in the section above.

References:

Alliance Policies:

200-2000 – New Member Materials

404-1101 – Utilization Management Program

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404-1113 – External Independent Medical Review
404-1714 – Technology Assessment
408-1305 – Behavioral Health Services
405-1306 – Community Care Coordination Services

Impacted Departments:

Care Management
Member Services
Pharmacy
Provider Services

Regulatory:

California Code of Regulations, Title 22, Article 4, sections 51303, 51340 and 51340.1
California Code of Regulations, Title 28, Section 1300.74.721
California Code of Regulations, Title 22, Section 51303(a) and 42 CFR 438.210 (a)(5)
Code of Federal Regulations, Title 42 of the USC, Section 1396d(r)(5)
42 USC, section 1396d is available at:
[http://uscode.house.gov/view.xhtml?req=\(title:42%20section:1396d%20edition:prelim](http://uscode.house.gov/view.xhtml?req=(title:42%20section:1396d%20edition:prelim)
Health and Safety Code Sections 1340 et seq.
Health and Safety Code Sections 1374.72(a)(3)(A); Section 1374.721(f)(1); Section 1374.721(b);
Section 1374.72(h)
Health and Safety Code section 1363.5

Legislative:


Senate Bill, SB-586 Whole Child Model - Children's Services
Senate Bill, SB-855 Mental Health and Substance Use Disorders Coverage

Contractual (Previous Contract):

Medi-Cal Contract, Exhibit A, Attachment 10, Provision 2
DHCS State Medi-Cal Contract [Final Rule] Exhibit A, Attachment 10, Provision 1.A
DHCS State Medi-Cal Contract [Final Rule] Exhibit A, Attachment 10, Provision 1.B
DHCS State Medi-Cal Contract [Amendment 46] Exhibit A, Attachment 10, Provision 2
DHCS State Medi-Cal Contract [Final Rule Amendment 46] Exhibit A, Attachment 10, Provision 2
DHCS State Medi-Cal Contract [Final Rule] Exhibit EA, Attachment 10, Definitions Provision 2.
DHCS State Medi-Cal Contract [Amendment 46] Exhibit A, Attachment 10, Provision 5.E.
DHCS State Medi-Cal Contract [Final Rule] Exhibit E, Attachment 1, Definitions
DHCS State Medi-Cal Contract (2024), Exhibit A, Attachment 3, Provision 2.2.6.I

Contractual (2024 Contract):

Medi-Cal Contract, Exhibit A, Attachment 3, Provision 2.3.1.C.-D.
Medi-Cal Contract, Exhibit A, Attachment 3, Provision 5.3.1.D
Medi-Cal Contract 2024, Exhibit A, Attachment 3, Provision 5.3.1.E

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Medi-Cal Contract, Exhibit A, Attachment 3, Provision 5.3.2

DHCS All Plan Letter:

APL 22-006, Medi-Cal Managed Care Plan Responsibilities for Non-Specialty Mental Health Services

APL 23-005 Requirements for Coverage of Early and Periodic Screening, Diagnostic, and Treatment Services for Medi-Cal Members Under the Age of 21

DMHC All Plan Letters:

APL 21-002, Implementation of Senate Bill 855, Mental Health and Substance Use Disorders Coverage

APL 24-007, Implementation of Senate Bill 855, Mental Health and Substance Use Disorders Coverage

NCQA (Effective 03/15/2024):

UM 2: Element A: UM Criteria: Factor 4 & 5

Supersedes:

Policy 401-1506 – Medical Necessity

APL 19-010 Requirements for Coverage of EPSDT for Medi-Cal Members Under the Age of 21 is superseded by 23-005

Other References:

Alliance Medi-Cal Evidence of Coverage (EOC)

Evidence of Coverage (EOC) Alliance Knox Keene Lines of Business

DMHC Claims Management Assessment TAG 7 November 1, 2005: Appendix B Glossary of Terms

National Committee for Quality Assurance (NCQA) 2018 Health Plan Standards and Guidelines for the Accreditation of Health Plans

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
01/30/2023	01/30/2023	Paige Harris, Regulatory Reporting Supervisor	UMWG
03/27/23	03/27/2023	Paige Harris, Regulatory Reporting Supervisor	UMWG

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6/23/2023	6/23/2023	Danah Hernandez, Regulatory Reporting Supervisor	UMWG
8/4/2023	8/4/2023	Carissa Grepo, RN UM Manager – Prior Auth	UMWG
10/23/2023	10/23/2023	Danah Hernandez, Regulatory Reporting Supervisor	UMWG
3/15/2024	3/15/2024	Carissa Grepo, RN UM Manager – Prior Auth	UMWG
11/05/2024	11/05/2024	Kelly Tlemcani, Business Analyst II	UMWG