Policy:	GG.1401
Title:	**Physician Administered Drug (PAD) Prior Authorization Process**
Department:	Medical Management
Section:	Pharmacy Management
CEO Approval:	*/s/ Michael Hunn 05/09/2024*
Effective Date:	01/01/1996
Revised Date:	03/01/2024
Applicable to:	☒ Medi-Cal ☐ OneCare ☐ PACE ☐ Administrative

I. PURPOSE

This policy defines CalOptima Health's Physician Administered Drug (PAD) Prior Authorization (PA) process.

II. POLICY

A. CalOptima Health shall require a Prior Authorization for medications and supplies that are listed on the PAD PA List.

B. CalOptima Health shall maintain appropriate communication with the Provider and/or Member or the Member's Authorized Representative throughout the PA process to facilitate delivery of appropriate services.

C. CalOptima Health shall provide a written response of approve, modify, defer for Medical Necessity information from the Provider, or deny to an authorization within twenty-four (24) hours of receipt of an expedited (preservice or concurrent) or standard request and thirty (30) calendar days for a retrospective request to the Provider.

D. A decision to modify or deny an expedited (preservice or concurrent) or standard request shall be communicated to the Member in writing within twenty-four (24) hours of receipt of the request with information reasonably necessary to make a determination.

E. A decision to modify or deny can only be made by a CalOptima Health Pharmacist or Medical Director.

F. For appropriately prescribed pain management medications for terminally ill patients when Medically Necessary, CalOptima Health shall approve, modify, defer for information reasonably necessary to make a determination, or deny a PA in a timely fashion, appropriate for the nature of the Member's condition, and not to exceed twenty-four (24) hours of the CalOptima Health's receipt of the information requested by the plan to make the decision.

1. If the request is modified, denied, or delayed due to lack of information reasonably necessary to make a determination is required, CalOptima Health shall contact the provider within twenty-four (24) hours of receipt of the information requested by CalOptima Health to make the decision, with an explanation of the reason for the modification, denial or the need for additional information.

2. Only licensed physicians or health care professionals (competent to evaluate the clinical issues) make decisions to modify, deny, or delay (due to lack of information reasonably necessary to make a determination) a PA for pain management for terminally ill patients.

3. The requested treatment shall be deemed authorized as of the expiration of the applicable timeframe.

G. CalOptima Health shall require the use of a U.S. Food and Drug Administration (FDA)-approved and nationally marketed drugs, unless Medical Necessity can be established requiring the use of a compounded alternative. Compounded products may be dispensed only when an FDA-approved therapeutic equivalent does not exist in the marketplace or when the FDA-approved product does not meet the medical needs of the Member and a compound alternative is Medically Necessary.

H. CalOptima Health Pharmacy Management shall require generic substitution when an equivalent generic product is available for Members not meeting the following criteria:

1. CalOptima Health Pharmacy Management adheres to Title 22, Section 51003 of the California Code of Regulations: Authorization may be granted only for the lowest cost item or service covered by the program that meets the Member's medical needs.

2. CalOptima Health Pharmacy Management shall utilize the FDA bioequivalent ratings when requiring generic substitution. The FDA has rated all generic drugs "A" or "B." Only "A" rated products are considered bioequivalent and interchangeable to the brand-name equivalents by the FDA.

I. If CalOptima Health fails to issue a NOA for Prior Authorization requests within the required time frame, it shall be considered a denial and shall constitute an Adverse Benefit Determination. The Member shall have the right to request an Appeal in accordance with CalOptima Health Policy GG.1510 Member Appeal Process.

J. Members newly enrolled in the Whole-Child Model program shall be permitted to continue use of any currently prescribed medication, including PADs, that is part of a prescribed therapy for the Member's California Children's Services (CCS)-Eligible Condition or conditions immediately prior to the date of transition of responsibility for the Member's CCS services to CalOptima Health, whether or not the drug requires a Prior Authorization, until the Member's prescribing CCS Provider has completed an assessment of the child or youth, created a treatment plan, and decides that the particular medication is no longer Medically Necessary, or the medication is no longer prescribed by the Member's CCS Provider. In such cases, CalOptima Health must send a NOA to the CCS-eligible Member informing them of the service change, as well as their Appeal rights.

K. CalOptima Health Pharmacy Management shall review and update the CalOptima Health Prior Authorization guidelines when appropriate and, at a minimum, on an annual basis.

L. CalOptima Health shall ensure the Prior Authorization process for medications and supplies is consistently applied to medical/surgical, mental health, and substance use disorder medications and supplies.

1. Quantity limits and utilization management restrictions shall not be applied more stringently on mental health and substance abuse disorder drugs as compared to medical/surgical drugs.

2. Financial requirements or treatment limitations for mental health and substance abuse disorder drugs shall not be more restrictive than those applied to medical/surgical drugs.

III. PROCEDURE

A. A Provider or Practitioner shall submit a fully completed Authorization Request Form (ARF) including physician signature or written physician order, as well as current medical documentation supporting the need for the requested services to the CalOptima Health UM Department by:

1. Mail to:
   Attn: Utilization Management Department
   CalOptima Health
   P.O. Box 11033
   Orange CA 92856;

2. Telephone;

3. Facsimile; or

4. A contracted Provider may submit an authorization request online via CalOptima Health Link. The contracted Provider must upload medical documentation to CalOptima Health Link to support the Medical Necessity of the requested services.

B. CalOptima Health, shall review and classify all PA requests based on the following:

1. Urgent Pre-Service Request;

2. Urgent Concurrent Request;

3. Standard Request (non-urgent Pre-Service Request); and

4. Post-Service Request.

C. CalOptima Health shall review all PA requests based on the Member's individual needs, in accordance with criteria established by the CalOptima Health PA guidelines for drug utilization review that are consistent with current medical practice and the Title 22, California Code of Regulations definition of Medical Necessity, and that have been approved by CalOptima Health's Pharmacy and Therapeutics (P&T) Committee. Requests shall also be evaluated by CalOptima Health to consider the Member's condition, age, gender, Health Network (to ensure appropriate responsibility for coverage), place of residence, and for other payers or other insurance coverage. CalOptima Health shall obtain all clinical information, relevant to a Member's care, to render a decision. Requests that do not meet the CalOptima Health PA Guidelines shall be reviewed by a CalOptima Health Clinical Pharmacist and/or Medical Director.

1. A CalOptima Health Clinical Pharmacist or Medical Director shall review all PA requests, and render a response within twenty-four (24) hours of receipt of the PA request. A response includes an approval, modification, deferral or denial.

2. If the PA request has sufficient clinical information to meet the CalOptima Health PA guidelines, CalOptima Health shall approve the PA and notify the Provider by facsimile within twenty-four (24) hours of receipt of the PA request.

3. If the PA request has insufficient information to meet the CalOptima Health PA guidelines, CalOptima Health shall defer the PA for additional Medical Necessity information and notify the Provider by facsimile.

   a. The notice shall include a reason for the deferral and date of when a response is needed to render

a decision.

4. If all information reasonably necessary is received and the information provided by the Provider is insufficient for approval, CalOptima Health shall render a decision within twenty-four (24) hours of receipt of the additional information.

5. In the event that all information reasonably necessary to make a determination was not received within the initial seventy-two (72) hours for expedited requests and fourteen (14) calendar days for standard requests, CalOptima Health may extend the timeframe of an authorization request once, for an additional fourteen (14) calendar days, if the Member or the Provider requested for an extension, or CalOptima Health can provide justification upon request by the Department of Health Care Services (DHCS) the need for additional information and how it is in the Member's interest. If the extension was not requested by the Member, CalOptima Health shall make reasonable efforts to give the Member and Prescribing Provider oral notice of the delay.

6. The Prescribing Provider and the Member shall be provided with an electronic Notice of Action (NOA) within twenty-four (24) hours of the decision. The NOA shall include the reason for the extension, the additional information needed to render the decision, the type of expert needed to review, and/or the additional examinations or tests required and the anticipated date on which a decision will be rendered. CalOptima Health shall send the NOA pursuant to Section III.E. of this Policy.

D. CalOptima Health shall notify the Member and Provider, of any denial, delay, modification, termination, suspension, or reduction of the level of treatment or services currently underway, or medication carve out, in a written NOA, in accordance with CalOptima Health Policy GG.1507: Notification Requirements for Covered Services Requiring Prior Authorization.

E. The written NOA shall contain information as required by applicable state and federal regulations and outlined in the CalOptima Health Policy GG.1507: Notification Requirements for Covered Services Requiring Prior Authorization. It shall also:

1. Provide a statement of action CalOptima Health is taking on the request;

2. Clearly and concisely describe the specific reason(s) for the deny, modify, delay, termination, suspension, reduction of the level of treatment or services currently underway, or medication carve out decision in easy to understand language and provide a reference to the CalOptima Health PA Guidelines on which the decision was based;

3. Contain all of the following for decisions based in whole or in part on Medical Necessity:

   a. Provide a description of the criteria or guidelines used to include a reference to the specific regulation or authorization procedures that support the decision, as well as an explanation of the criteria or guidelines;

   b. Describe the clinical reasons for the decision and explicitly state how the Member's condition does not meet the criteria or guidelines;

4. Describe how the Provider can obtain the medication for PA requests that exceed the quantity limit. CalOptima Health shall advise the Provider how to fill a prescription for a lesser quantity when a denial is made on the basis of quantity limit;

5. Describe how the Provider can obtain an alternative drug that does not require a PA (if applicable);

6. Define how the Provider may request, free of charge, copies of all documents and records relevant to the NOA, including the actual benefit provision, guideline, protocol, or other criteria on which the decision was based;

7. Inform the Provider of the availability of an appropriate practitioner to discuss the denial and provide contact instructions;

8. Include the Member and Provider's Appeal rights, an explanation of the Appeal process, and instructions on how to submit an Appeal;

9. Explain that the Member or Provider can provide written comments, documents, or other information to Appeal the denial;
10. Include the name and direct telephone number of the decision maker on the Provider notification; and

11. Include a "Your Rights" attachment, along with the nondiscrimination notice and language assistance taglines, as set forth in CalOptima Health Policy GG.1507: Notification Requirements for Covered Service Requiring Prior Authorization.

F. CalOptima Health shall communicate the decision to deny, delay, modify, terminate, suspend, or reduce the level of treatment or services currently underway, or of a medication carve out to the Member, in writing, which shall be dated and postmarked within twenty-four (24) hours of receipt of the request with information reasonably necessary to make a determination.

G. CalOptima Health shall notify the Provider of the decision to approve, deny, delay, modify, terminate, suspend, or reduce the level of treatment or services currently underway, or of a medication carve out. The written notification of the decision shall be dated within twenty-four (24) hours of receipt of the request with information reasonably necessary to make a determination.

H. In accordance with CalOptima Health Policy GG.1510: Member Appeal Process, a Provider, Member, or Member's Authorized Representative may Appeal any decision that involves the delay, modification, or denial of services based on Medical Necessity, termination, suspension, or reduction of the level of treatment or services currently under way, or a determination that the requested service was not a covered benefit within sixty (60) calendar days from the date on the NOA.

I. For terminations, suspensions, or reductions of previously authorized services, CalOptima Health shall notify Members at least ten (10) calendar days before the date of the action, with the exception of circumstances permitted under Title 42 of the Code of Federal Regulations (CFR), Sections 431.213, 431.214 and 438.420.

IV. ATTACHMENT(S)

Not Applicable

V. REFERENCE(S)

A. 2023 NCQA Health Plan Accreditation-UM Standards
B. California Business and Professions Code, Section 4039
C. California Health and Safety Code, Section 1367.01 and 1367.215(a)
D. California Welfare and Institutions Code, Sections 14185 and 14094.13(d)
E. CalOptima Health Physician Administered Drug Prior Authorization Required List (PAD PA List).
F. CalOptima Health Contract with the Department of Health Care Services (DHCS) for Medi-Cal
G. CalOptima Health Policy GG.1507: Notification Requirements for Covered Services Requiring Prior

Authorization
H. CalOptima Health Policy GG.1510: Member Appeal Process
I. Department of Health Care Services (DHCS) All Plan Letter (APL) 21-011: Grievance and Appeals Requirements, Notice and "Your Rights" Templates
J. Department of Health Care Services (DHCS) All Plan Letter (APL) 23-034: California Children's Services Whole Child Model Program
K. Department of Health Care Services (DHCS) Policy Letter (PL) 14-002: Requirement to Use Food and Drug Administration Approved Drugs, Rather Than Compounded Alternatives.
L. Social Security Act, § 1927(d)(5)(A)
M. Title 22, California Code of Regulations, §§ 51003, 51303, 53894 and 438.404
N. Title 42, California Code of Regulations, §§ 431.213-214, 438.10, 438.210(c),438.3(s)(6), 438.910(b)

VI. REGULATORY AGENCY APPROVAL(S)

Date	Regulatory Agency	Response
07/23/2014	Department of Health Care Services (DHCS)	Approved as Submitted
11/10/2015	Department of Health Care Services (DHCS)	Approved as Submitted
04/19/2016	Department of Health Care Services (DHCS)	Approved as Submitted
08/09/2016	Department of Health Care Services (DHCS)	Approved as Submitted
10/18/2018	Department of Health Care Services (DHCS)	Approved as Submitted
10/20/2022	Department of Health Care Services (DHCS)	Approved as Submitted
12/06/2023	Department of Health Care Services (DHCS)	File and Use
05/02/2024	Department of Health Care Services (DHCS)	Approved as Submitted

VII. BOARD ACTION(S)

Date	Meeting
09/06/2018	Regular Meeting of the CalOptima Board of Directors
04/01/2021	Regular Meeting of the CalOptima Board of Directors

VIII. REVISION HISTORY

Action	Date	Policy	Policy Title	Program(s)
Effective	01/01/1996	GG.1401	Prior Authorization Process of Medication: The CalOptima Health Pharmacy Authorization System (CPAS) Process	Medi-Cal
Revised	03/01/1999	GG.1401	Prior Authorization Process of Medication: The CalOptima Health Pharmacy Authorization System (CPAS) Process	Medi-Cal
Revised	05/01/1999	GG.1401	Prior Authorization Process of Medication: The CalOptima Health Pharmacy Authorization System (CPAS) Process	Medi-Cal
Revised	01/01/2001	GG.1401	Prior Authorization Process of Medication: The CalOptima Health Pharmacy Authorization System (CPAS) Process	Medi-Cal

Action	Date	Policy	Policy Title	Program(s)
Revised	03/01/2002	GG.1401	Prior Authorization Process of Medication: The CalOptima Health Pharmacy Authorization System (CPAS) Process	Medi-Cal
Revised	08/01/2003	GG.1401	Prior Authorization Process of Medication: The CalOptima Health Pharmacy Authorization System (CPAS) Process	Medi-Cal
Revised	04/01/2007	GG.1401	Pharmacy Authorization Process	Medi-Cal
Revised	07/01/2011	GG.1401	Pharmacy Authorization Process	Medi-Cal
Revised	01/01/2013	GG.1401	Pharmacy Authorization Process	Medi-Cal
Revised	01/01/2014	GG.1401	Pharmacy Authorization Process	Medi-Cal
Revised	05/01/2014	GG.1401	Pharmacy Authorization Process	Medi-Cal
Revised	03/01/2015	GG.1401	Pharmacy Authorization Process	Medi-Cal
Revised	10/01/2015	GG.1401	Pharmacy Authorization Process	Medi-Cal
Revised	02/01/2016	GG.1401	Pharmacy Authorization Process	Medi-Cal
Revised	06/01/2016	GG.1401	Pharmacy Authorization Process	Medi-Cal
Revised	12/01/2016	GG.1401	Pharmacy Authorization Process	Medi-Cal
Revised	07/01/2017	GG.1401	Pharmacy Authorization Process	Medi-Cal
Revised	09/06/2018	GG.1401	Pharmacy Authorization Process	Medi-Cal
Revised	01/01/2019	GG.1401	Pharmacy Authorization Process	Medi-Cal
Revised	04/01/2021	GG.1401	Pharmacy Authorization Process	Medi-Cal
Revised	11/01/2021	GG.1401	Pharmacy Authorization Process	Medi-Cal
Revised	07/01/2022	GG.1401	Pharmacy Authorization Process	Medi-Cal
Revised	01/01/2023	GG.1401	Physician Administered Drug (PAD) Prior Authorization Process	Medi-Cal
Revised	11/01/2023	GG.1401	Physician Administered Drug (PAD) Prior Authorization Process	Medi-Cal
Revised	03/01/2024	GG.1401	Physician Administered Drug (PAD) Prior Authorization Process	Medi-Cal

IX. GLOSSARY

Term	Definition
Appeal	A review by CalOptima Health of an adverse benefit determination, which includes one of the following actions: 1. A denial or limited authorization of a requested service, including determinations based on the type or level of service, requirements for Medical Necessity, appropriateness, setting, or effectiveness of a Covered Service; 2. A reduction, suspension, or termination of a previously authorized service; 3. A denial, in whole or in part, of payment for a service; 4. Failure to provide services in a timely manner; or 5. Failure to act within the timeframes provided in 42 CFR 438.408(b).
Authorized Representative	A person designated by the Member or a person who has the authority under applicable law to make health care decisions on behalf of adults or emancipated minors, as well as parents, guardians or other persons acting in loco parentis who have the authority under applicable law to make health care decisions on behalf of unemancipated minors.
Concurrent Request	A request for coverage of pharmaceutical services made while a Member is in the process of receiving the requested pharmaceutical services, even if the organization did not previously approve the earlier care.
Grievance	An oral or written expression of dissatisfaction about any matter other than an action that is an adverse benefit determination, as identified within the definition of an Appeal, and may include, but is not limited to: the quality of care or services provided, interpersonal relationships with a Provider or CalOptima Health's employee, failure to respect a Member's rights regardless of whether remedial action is requested, and the right to dispute an extension of time proposed by CalOptima Health to make an authorization decision.
Health Network	A Physician Hospital Consortium (PHC), physician group under a shared risk contract, or health care service plan, such as a Health Maintenance Organization (HMO) that contracts with CalOptima Health to provide Covered Services to Members assigned to that Health Network.
Health Risk Assessment	A health questionnaire, used to provide Members with an evaluation of their health risks and quality of life.
Individual Care Plan	A plan of care developed after an assessment of the Member's social and health care needs that reflects the Member's resources, understanding of his or her disease process, and lifestyle choices.

Medically Necessary or Medical Necessity	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 Title 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 service is Medically Necessary if it meets the Early and Periodic Screening, Diagnostic and Treatment (EPSDT) standard of medical necessity set forth in Section 1396d(r)(5) of Title 42 of the United States Code, as required by W&I Code 14059.5(b) and W&I Code Section 14132(v). Without limitation, Medically Necessary services for Members under 21 years of age include Covered Services necessary to achieve or maintain age-appropriate growth and development, attain, regain or maintain functional capacity, or improve, support or maintain the Member's current health condition. CalOptima Health shall determine Medical Necessity on a case-by-case basis, taking into account the individual needs of the child.
Member	A Medi-Cal eligible beneficiary as determined by the County of Orange Social Services Agency, the California Department of Health Care Services (DHCS) Medi-Cal Program, or the United States Social Security Administration, who is enrolled in the CalOptima Health program.
Post-Service Request	A request for coverage of pharmaceutical services that have been received by a Member, e.g., retrospective review.
Pre-Service Request	A request for coverage of pharmaceutical services that CalOptima Health must approve in advance, in whole or in part.
Prior Authorization	A formal process requiring a health care Provider to obtain advance approval of Covered Services Medically Necessary and to what amount, duration, and scope, except in the case of an emergency.
Provider	A physician, nurse, nurse mid-wife, nurse practitioner, medical technician, physician assistant, hospital, laboratory, ancillary provider, or other person or institution that furnishes Covered Services.
Whole Child Model (WCM)	An organized delivery system established for Medi-Cal eligible CCS children and youth, pursuant to California Welfare & Institutions Code (commencing with Section 14094.4), and that (i) incorporates CCS covered services into Medi-Cal managed care for CCS-eligible Members and (ii) integrates Medi-Cal managed care with specified county 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.