Medi-Cal Rx Prior Authorization (PA)/Utilization Management (UM) and Related Appeals Processes
Version 3.1; *Current as of 11/05/2021*

This document outlines the Department of Health Care Services (DHCS') fee-for-service (FFS) Medi-Cal PA/UM and related appeals processes, which align with and build upon existing Medi-Cal FFS processes/protocols for the Medi-Cal program more broadly. In partnership with the Medi-Cal Rx Contractor, Magellan Medicaid Administration, Inc. (Magellan), DHCS is committed to implementing and overseeing[1] effective Medi-Cal Rx PA/UM and related appeals processes to ensure appropriate triaging, referral, and/or disposition of all pharmacy-related requests for PA, including beneficiary appeals through the existing Fair Hearing process. The Medi-Cal Rx PA/UM and related appeals processes will be in effect when Medi-Cal Rx enters full assumption of operations.

Please note that this document does not address the Medi-Cal Rx complaints and grievances policy, which is separate and apart from appeals in the Medi-Cal FFS delivery system. For more information, the full Medi-Cal Rx complaints and grievances policy is available on DHCS' website at: https://www.dhcs.ca.gov/provgovpart/pharmacy/Pages/Medi-CalRX.aspx.

Definitions

For purposes of this process document, the following definitions apply:

- "Prior Authorization" (PA) refers to a request for coverage of Medi-Cal Rx pharmacy benefit or services, which includes documentation establishing that the requested pharmacy benefit or service is medically necessary or a medical necessity for the Medi-Cal beneficiary based upon an individualized assessment by their treating health care practitioner of applicable evidence-based criteria or guidelines. PAs can be approved (full or modified), deferred, or denied.

- "Utilization Management" (UM) refers to the use of various techniques and strategies, such as PA or claim edits, which allow DHCS, like Medi-Cal managed care plans (MCPs) and other public and private payers, to ensure that all benefits or services are medically appropriate for the beneficiary based upon

[1] DHCS, and its contracted partner, will ensure compliance with contractual obligations utilizing existing program integrity and internal audit functionalities.

evidence-based criteria or guidelines before those benefits or services are provided.

- "Medically necessary" and "medical necessity" are used interchangeably. Consistent with the federal requirements of Subchapter XIX (commencing with Section 1396) of Chapter 7 of Title 42 of the United States Code (USC) as well as California state law, W&I Code Section 14059.5, medical necessity is defined, in relevant part, as follows:

  - For individuals 21 years of age or older, consistent with the federal requirements of Subchapter XIX (commencing with Section 1396) of Chapter 7 of Title 42 of the United States Code (USC) as well as California state law, Welfare and Institutions (W&I) Code Section 14059.5, the Medi-Cal Provider Manual will include the following definition:

    i. "(a) For individuals 21 years of age or older, a service is 'medically necessary' or a 'medical necessity' when it is reasonable and necessary to protect life, to prevent significant illness or significant disability, or to alleviate severe pain."

  - For individuals under 21 years of age, Consistent with the federal requirements of Subchapter XIX (commencing with Section 1396) of Chapter 7 of Title 42 of the USC as well as California state law, W&I Code Section 14059.5, the Medi-Cal Provider Manual will include the following definition:

    ii. (b)(1) For individuals under 21 years of age, a service is "medically necessary" or a "medical necessity" if the service meets the standards set forth in Section 1396d(r)(5) of Title 42 of the USC.

  - Additionally, consistent with federal requirements enumerated in the Social Security Act (SSA) Section 1905(a) and state law[2], under the Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) benefit for Medi-Cal beneficiaries under age 21, the Medi-Cal Provider Manual language clarifies that services are covered so long as the service is medically necessary to "correct or ameliorate" any defects and physical and mental illnesses or conditions. The language also clarifies that under EPSDT, covered benefits include all medically necessary services that are included within the categories of mandatory and optional services (as defined under

[2] W&I Code Section 14059.5.

listed in the SSA Section 1905(a)), regardless of whether or not they are specifically enumerated in California's Medicaid State Plan.[3]

- "Adverse Benefit Determination" is the denial or limited authorization (modification) of a requested service, including determinations based on the type or level of service, medical necessity, appropriateness, setting or effectiveness of a covered benefit and includes the reduction, suspension or termination of a previously authorized service.
- "Appeals" for the purposes of the Medi-Cal Appeals Process, are defined as when an individual disagrees with a benefit or eligibility-related decision, such as coverage disputes, disagreeing with and seeking reversal of a request for PA involving medical necessity, etc. and files a request for Fair Hearing.
- "Notice of Action" (NOA) refers to a written notice sent to Medi-Cal beneficiaries when a PA is submitted for new services or reauthorization of services, the services have not yet been provided, and the decision is a denial or limited authorization (modification) of the requested services. NOAs include information about Medi-Cal beneficiary Fair Hearing rights and how to appeal the decision if they disagree with the information in the NOA.[4]
- "Medi-Cal Fair Hearing", "State Hearing", and "Fair Hearing" all refer to the administrative process, overseen by the California Department of Social Services (CDSS) and adjudicated by an Administrative Law Judge (ALJ) accessible by Medi-Cal beneficiaries upon generation of a NOA relative to Medi-Cal Rx pharmacy services or benefits that have been denied or modified.
- "ALJ" refers to the licensed attorneys who adjudicate Fair Hearing requests and are employed by CDSS for this purpose.
- "Authorized Representative" refers to an individual or organization appointed as your Medi-Cal authorized representative to act for you on all duties (such as complete and sign redetermination forms, help with fair hearings and appeals, etc.) related to your Medi-Cal eligibility and enrollment.

[3] For more detailed information, please refer to the EPSDT section of the Medi-Cal Provider Manual (*epsdt),* which is available on DHCS' website at: https://files.medi-cal.ca.gov/pubsdoco/Manuals_menu.aspx.
[4] Please see definition for Adverse Benefit Determination in APL 17-006 https://www.dhcs.ca.gov/formsandpubs/Documents/MMCDAPLsandPolicyLetters/APL2017/APL17-006.pdf

Medi-Cal Rx PA/UM Processes

DHCS, in partnership with Magellan, will accept and process PA requests and provide a response to the submitting Medi-Cal provider within 24 hours of receiving a PA request, pursuant to applicable state law (W&I Code Section 14133.37).

Medi-Cal providers are responsible for submitting PA request to DHCS, and providing the appropriate documentation[5] to substantiate clinical appropriateness and medical necessity for an individual beneficiary. Medi-Cal providers are expected to keep this information in the Medi-Cal beneficiary's medical record, which should be available to DHCS upon request.

Medi-Cal Rx PA requests are adjudicated as follows:

- For certain drug categories Medi-Cal Rx PA requests will first be processed for medical necessity requirements that may be met using data already known to Medi-Cal Rx (e.g. medical necessity criteria established through lookback of historical claims). If medical necessity requirements are met in this process step then a PA is approved without additional review.

- Customer Service Center (CSC) agents, including Certified Pharmacy Technicians (CPT), nurses, and pharmacists evaluate requests for prior authorization received via paper, Fax, and electronic requests (that are not initially approved), for complete documentation, eligibility, and program coverage. The request is also evaluated for adherence to the Medi-Cal Rx pharmacy coverage policy established by DHCS. In addition, MCP clinicians may provide input to prior authorization cases through Clinical Liaisons.

  Based upon the PA submission, supporting documentation provided by the submitting Medi-Cal provider (e.g., chart notes, visit summaries, test/lab/diagnostic results, etc.), clinical documentation provided by MCPs or others, and evaluation by the PA adjudicator of evidence-based medicine and clinical best practices (e.g., randomized, controlled trials; peer-reviewed journals; evidence-based literature; policy guidance from nationally recognized organizations, etc.) relative to the requested benefit or service, the PA adjudicator will make a determination based upon medical necessity for a Medi-Cal beneficiary on an individualized, case-by-case basis.

- Actions that may be taken in this step includes approval (full or modified), deferral, or denial recommendation (note: if Magellan's CPT or nurse initially

[5] A list of information required to accompany a PA request can be found in the TAR Overview section of the Medi-Cal Provider Manual under "TAR Information Requirements." The TAR Overview section also specifies where to find the criteria used to adjudicate the treatment authorization requests, which should assist Medi-Cal providers with clearly articulating and documenting the medical necessity for the requested services and benefits

recommends a denial of the PA request, it will be submitted for additional clinical review by a licensed pharmacist employed by Magellan).

- For approvals (full or modified), notification will be sent back to the submitting provider (pharmacy or prescriber) confirming that the PA request has been approved.

- For deferrals, notification will be sent back to the submitting provider, seeking the necessary information to act on the PA request. The submitting provider will then have 30 calendar days to send the additional information requested by Magellan that is necessary to adjudicate the PA request. Thereafter, two outcomes can occur:

  - If, after 30 days, the submitting provider has not sent the additional information, Magellan will deny the PA request, and notification will be sent back to the submitting provider confirming that the PA request has been denied. (Denials for not providing requested information are not referred to DHCS for final determination.)

  - If, within 30 days, the submitting provider sends the additional information and it establishes medical necessity, Magellan will take appropriate action to approve the PA request, and notification will be sent back to the submitting provider confirming that the PA request has been approved.

  - If, within 30 days, the submitting provider sends the additional information and it does not establish medical necessity, Magellan will recommend denial and refer to DHCS for final disposition.

- For denials, the recommendation will be referred to DHCS for final disposition by a DHCS pharmacist who will review all of the documentation and make a determination to accept Magellan's recommendation to deny the PA request, reject it and approve (full or modified) the PA request, or defer the PA request for additional information.

  - In reviewing all Medi-Cal Rx PA requests, DHCS' pharmacists will base decisions on current best practices and evidence-based clinical guidelines/literature relative to the Medi-Cal Rx pharmacy benefit or service being requested in the PA.

    - In addition, when necessary (e.g., for cases involving Medi-Cal beneficiaries with complex and/or specialized health care needs), DHCS shall utilize other appropriate clinical professionals, such as

nurses and physicians, with expertise in the requested treatment, as needed to ensure PA requests are based on sound clinical findings that support the medical necessity of the Medi-Cal Rx pharmacy benefit or service being requested in the PA.

- If DHCS' pharmacist supports Magellan's final recommendation for denial of the PA request, notification will be sent to the submitting provider confirming that the PA request has been denied.

- If DHCS' pharmacist decides to approve the request for PA (full or modified), notification will be sent to the submitting provider confirming that the request for PA has been approved.

- If the final decision is to deny (or approve but modify) a Medi-Cal Rx request for PA, known as an Adverse Benefits Determination, Medi-Cal Rx will mail the Medi-Cal beneficiary a NOA consistent with applicable state and federal requirements, and provide a copy to the submitting provider.[6]

Medi-Cal is providing a pharmacy transition period for the first 180 days after full assumption of operations, with over 15 months of historical PAs and claims/encounters from FFS and MCPs loaded into Medi-Cal Rx for 'grandfathering' and 'lookback' processes to facilitate a smooth and effective transition to Medi-Cal Rx for beneficiaries.[7] In addition, existing FFS systems will remain available for inquiries post-full assumption of operations.

Medi-Cal Rx Beneficiary Appeals (Fair Hearing) Processes

Based upon the Medi-Cal Rx PA/UM processes described above, if following a denial (or modified approval) of a Medi-Cal Rx pharmacy benefit or service, a Medi-Cal beneficiary disagrees with DHCS' Adverse Benefit Determination, also known as a Notice of Action (NOA), relative to Medi-Cal Rx pharmacy benefits or services, they may file a request for a Fair Hearing through CDSS, consistent with applicable state and federal statutes and regulations, including but limited to: W&I Code Sections 10950-10967, Title 42 of the Code of Federal Regulations (CFR) Sections 431.200 *et seq.*, and Title 22 of the California Code of Regulations (CCR), Sections 51014.1 and 51014.2.

Medi-Cal Rx beneficiaries will not be required to exhaust any internal and/or administrative DHCS processes prior to requesting a Medi-Cal Fair Hearing through CDSS. If DHCS/Magellan receives a beneficiary appeal request through the Medi-Cal Rx CSC, the callers will be triaged and provided the most appropriate contact information so they can submit their request for a Medi-Cal Fair Hearing, as

[6] For more information about NOA requirements in state and federal law, please see 22 CCR 51014.1,.
[7] For more information, please see DHCS' Pharmacy Transition Policy.

described in this document. Magellan will not be handling any beneficiary appeals issues relative to Medi-Cal Rx.

For more information about the existing Fair Hearing appeals process beyond what is contained in this document, please see DHCS' existing Fair Hearing policy and processes, which is available on DHCS' and CDSS' websites, respectively, at the following links:

- DHCS: https://www.dhcs.ca.gov/services/medi-cal/Pages/Medi-CalFairHearing.aspx

- CDSS: https://www.cdss.ca.gov/hearing-requests

All Medi-Cal Rx beneficiary appeals processes, including generation and distribution of pharmacy-related NOAs, will be conducted in a manner that is consistent with DHCS' existing requirements relative to threshold languages, including but not limited to providing interpreter and translation services and requested alternative formats. As a reminder, DHCS' existing threshold languages (17 total) are Arabic, Armenian, Cambodian, Cantonese, English, Farsi, Hindi, Hmong, Japanese, Korean, Laotian, Punjabi, Russian, Spanish, Tagalog, Thai, and Vietnamese. Medi-Cal Rx does not change the existing appeals and associated Fair Hearing process.

Pre-Transition and Post-Transition Roles and Responsibilities

- All pharmacy-related beneficiary appeals for Medi-Cal Rx services provided on or after Medi-Cal Rx full assumption of operations, will be handled through Medi-Cal Rx utilizing the existing Medi-Cal Fair Hearing process, administered through CDSS, as previously mentioned.

- All Medi-Cal MCP beneficiary appeals that originated as a result of a Medi-Cal MCP decision relative to pharmacy-related services for which the Medi-Cal MCP was at risk for on or before March 31, 2021, must be resolved by the MCP

    - Note: The right of Medi-Cal MCP members to submit appeals to the Department of Managed Health Care, including but not limited to the right to Independent Medical Review, for pharmacy-related services provided by the Medi-Cal MCPs rendered on or before Medi-Cal Rx full assumption of operations are not impacted by Medi-Cal Rx.

Medi-Cal Fair Hearing Processes and Timelines

The below narrative provides a high-level outline of the Medi-Cal Fair Hearing processes and associated timelines. Please review the applicable state and federal statutes and regulations for specific requirements and timelines/deadlines.

- Medi-Cal beneficiaries have the right to ask for a Fair Hearing within 90 days from the date a NOA is provided[8,9]. If the request is for continuation of a service a beneficiary is already receiving (note: this is called "Aid Paid Pending", and beneficiaries may be allowed to continue receiving the benefit/service until an ALJ decides the case), they must ask for a Fair Hearing within 10 days of the date of mailing of the NOA or before the effective date of the action to receive "Aid Paid Pending".

    - Fair Hearings can be requested online, by phone, fax, mail or email.

    - The beneficiary may request an expedited Fair Hearing at the time the Fair Hearing is requested, or thereafter, if taking the time for a standard resolution could seriously jeopardize the enrollee's life, physical or mental health, or ability to attain, maintain or retain maximum function.

- For a standard Fair Hearing, the appeal decision must be released to the beneficiary within 90 calendar days of filing the Fair Hearing request.

- Once a Fair Hearing is requested, CDSS will schedule and conduct the hearing at a reasonable time, date (typically within 30 calendar days of receipt of the request), and place/modality (typically by phone, video or in the county office in the county of residence of the Medi-Cal beneficiary). Expedited hearings are generally scheduled as soon as possible while complying with notice requirements.

- Fair Hearing are conducted on the scheduled date by the CDSS ALJ (note: Medi-Cal beneficiaries are entitled to have language assistance provided, and invite an authorized representative to attend the Fair Hearing proceedings).

- The CDSS ALJs submit their Proposed Decision (PD) as soon as possible after the close of the record and within 5 business days of the close of the record in an expedited case.

- The DHCS director or their delegate generally has 30 days to respond to the ALJ's PD. These 30 days are included in the 90-day deadline for release of the decision. CDSS may request DHCS to conduct expedited reviews of ALJ PDs.

- Within 30 days after receiving the final decision rendered by an ALJ, if a Medi-Cal beneficiary is dissatisfied with the DHCS Director's adopted decision, they may request a rehearing pursuant to W&I Code Section 10960. The DHCS

[8] Please see W&I Code Section 10951, which indicates that, after 90 days and up to 180 days, the ALJ may decide if there is good cause for a late filing.
[9] Please see CDSS Fair Hearing website at https://www.cdss.ca.gov/hearing-requests for filing timeframes including COVID-19 extended filing time

Director or their delegate shall grant or deny the rehearing requests pursuant to the criteria set forth in W&I Code Section 10960.

- If the Medi-Cal beneficiary has requested a rehearing, all of the evidence in the case record, including the hearing testimony, the beneficiary's evidence and information provided by clinical and administrative professionals, shall be considered in determining whether the Director's original decision should be upheld or overturned.

- Whether or not the rehearing request is granted, Fair Hearing decisions are part of a larger legal system and are thus subject to additional judicial appeals. Ultimately, if a rehearing request is not granted and/or if the Medi-Cal beneficiary is not satisfied, they can always file a case with the applicable State of California court.

Provider Appeals

Providers can appeal Medi-Cal Rx PA denials and modifications. Providers will submit appeals of PA adjudication results, clearly identified as appeals, via fax (800-869-4325), the Medi-Cal Rx provider web portal, or they can be mailed to:

Medi-Cal CSC, Provider Claims Appeals Unit
P.O. Box 610
Rancho Cordova, CA, 95741-0610.

Medi-Cal Rx will acknowledge each submitted PA appeal within three (3) days of receipt and make a decision within 60 days of receipt. Medi-Cal Rx will send a letter of explanation in response to each PA appeal. Providers who are dissatisfied with the decision may submit subsequent appeals. Medi-Cal providers may seek a judicial review of the appeal decision, as authorized under state law. For more information about the Medi-Cal Rx provider PA appeal process, please visit the Medi-Cal Rx website.

Reporting

DHCS, as part of its ongoing commitment to process improvement and increasing transparency relative to Medi-Cal Rx will continue to evaluate various consumer access and quality considerations/issues both raised by our Medi-Cal MCPs and other key stakeholders relative to the transition. These efforts will include posting additional information on the Medi-Cal Rx website regarding implementation to enable the public and stakeholders to assess the transition of the Medi-Cal prescription drug benefit from Medi-Cal managed care to FFS.

In addition, no later than July 1, 2022~~1~~[10], DHCS will convene stakeholders to identify strategies and opportunities for better and more robust public reporting on matters related to Medi-Cal Rx Fair Hearings, as well as to help assess whether additional changes to the Medi-Cal Rx complaints and grievances and/or appeals processes are warranted future forward. DHCS will release more information on this stakeholder engagement in early 2022~~1~~, as it becomes available.

Additional Reference Materials & Other Resources

Federal and State Statutes:

- *Federal Law:* Title 42 CFR Section 431.220, which describes requirements regarding administrative fair hearings.
- *State Statute:* W&I Code Section:10950-10967
- *State Regulations:* Title 22 CCR Section 51014.1, which describes Fair Hearings Related to Denial, Termination or Reduction in Medical Services.

State Resource (for state website links, please see Part I, above):

- CDSS Manual of Policies and Procedures (MPP): https://www.cdss.ca.gov/Portals/9/Regs/4CFCMAN.pdf

[10] This revised timeline aligns the stakeholder outreach with the original 6-month post go-live timeframe, given the 1-year delay in the Medi-Cal Rx implementation.