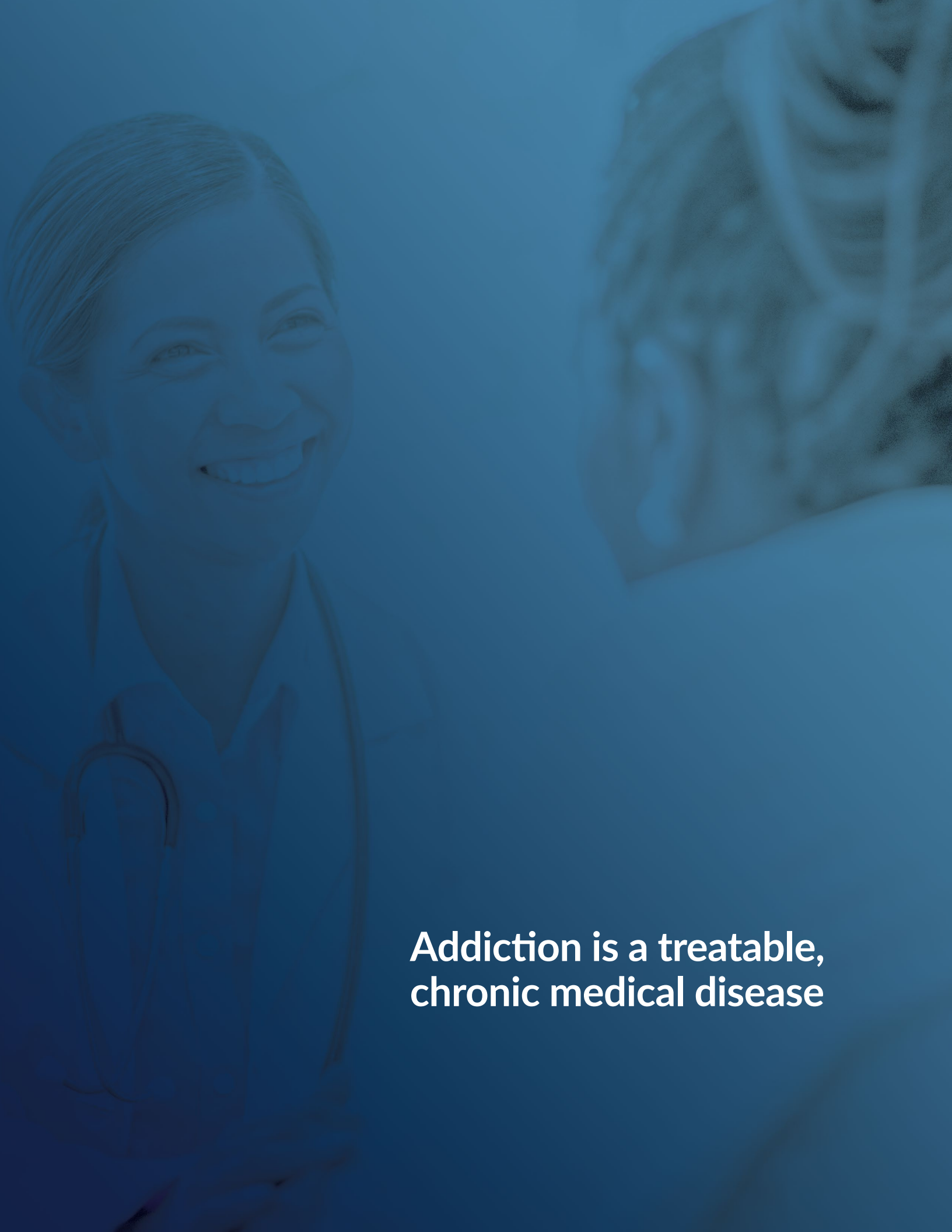




Utilization Management for Medications for Addiction Treatment Toolkit



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**Addiction is a treatable,
chronic medical disease**

Utilization Management for Medications for Addiction Treatment Toolkit

Introduction

Addiction is a treatable, chronic medical disease involving complex interactions among brain circuits, genetics, the environment and an individual's life experience. Medications are frequently used to treat addiction in conjunction with psychosocial interventions; however, prescribers can encounter challenges getting medications to their patients due to the complex health insurance payment system.

Health insurers (including commercial health plans, self-insured employers, and state Medicaid programs) frequently contract with third-party administrators called pharmacy benefit managers (PBMs) to manage the prescription drug benefit on behalf of the insurer.ⁱⁱⁱ For simplicity's sake, these actors will collectively be referred to as "payers" throughout this toolkit.

This toolkit is intended to give prescribers a broad overview of medication utilization management techniques and describe ways that prescribers can facilitate patient access to needed medications. It focuses on prescribed medications that are filled by retail pharmacies;

it does not cover the processes for methadone or specialty pharmacy products, such as injectable or implantable medications, all of which are commonly covered by a patient's medical benefit rather than their pharmacy benefit.

What is utilization management?

Utilization management (UM) is a set of techniques used by payers on behalf of purchasers of health-care benefits to manage healthcare costs, ensure services align with payers' medical necessity criteria, and reduce or eliminate care that is wasteful, inefficient, or unnecessary. These techniques include setting broad quality and payment standards for the covered population and influencing patient care decision-making through case-by-case assessment of the appropriateness of care prior to its provision. Ideally, UM sustains high quality care by ensuring that services follow generally accepted standards of care as defined by national medical specialty society-developed guidelines. For prescribers, however, UM can be frustrating and, if not

navigated correctly, lead to delays in patient treatment.

Medications for addiction treatment are subject to several types of UM, including prior authorization, medical necessity review, formulary restrictions, quantity and dose limits, and step therapy. Although unpopular among prescribers, payers use UM techniques (1) to direct prescribers to less expensive branded or generic medications, (2) to help ensure adherence to standards of care, (3) to identify dangerous medication interactions that prescribers may miss, particularly in cases where patients are receiving medications from multiple providers, and (4) control costs. Payers are strictly regulated and must conform to a wide range of constraining state and federal law and regulation.

Formularies

A prescription drug formulary is a list of approved drugs that a health plan, often through the help of a PBM, has agreed to cover, and defines the prescription drug benefit.ⁱⁱⁱ Medications on a formulary are usually grouped into tiers, which determine the patient's portion of the cost. When a patient's needed medica-

tion is not on the formulary of the patient's health plan, the patient will either need to pay out of pocket for the entire cost of the medication or the prescriber will need to submit an exception request to request coverage of the medication.

Prior Authorization

Prior authorization – sometimes referred to as preauthorization, prospective review, or prior review – is a process by which a service or treatment, such as a medication, is subject to review and approval before it will be covered. Prior authorization typically requires a demonstration of medical necessity, discussed in more detail below, along with documentation that the medication is appropriate for the patient. Once prior authorization documentation is received, reviewed, and approved, the insurance company will cover the medication according to the terms of the patient's health plan. Even if a medication is on the formulary of the patient's health plan, the medication may neverthe-

less be subject to prior authorization restrictions that must be met in order for the cost of the medication to be covered according to the terms of the patient's plan.

Step Therapy

Step therapy, sometimes referred to as a “fail first” protocol, requires a patient to try one medication before a different, usually more expensive, medication will be covered. Sometimes step therapy may require a member to try a short-acting medication before moving to a long-acting one, consistent with safety concerns. As examples, payers may prefer a certain formulation of a transmucosal buprenorphine medication, and some payers require step therapy for implantable or extended-release injectable buprenorphine.^{iv} Like prior authorization, a prescriber will need to submit documentation before the medication will be covered. Generally, unless an exception request is submitted and accepted, the prescriber will need to demonstrate that the patient has undergone the step therapy protocol before the payer will cover the medication.

Medical Necessity Review

Medical necessity review is needed when a clinician prescribes a medication for which the payer protocol requires review, such as the scenarios discussed above. Although the definition of medical necessity varies by state and payer, it is generally understood to mean that a prescribed medication or therapy is one that a prescriber, exercising prudent clinical judgment in accordance with the generally accepted standard of care, would provide to a patient for the purposes of evaluating, diagnosing, or treating an illness, disease, or its symptoms.^v Medical necessity review for medications for addiction treatment requires that the patient be diagnosed with an underlying disorder, such as opioid use disorder, for which the medication is appropriate. Medical necessity is almost always one condition that must be met as part of a prior authorization or step therapy review. If a prescribed medication meets established medical necessity criteria, and the medication is a covered benefit, it is approved. If it does not meet medical necessity criteria or is not a covered benefit, the legal obligation of the payer is to deny the request.

Quantity and Dose Limits

Payers frequently impose quantity or dose limits on medications, often in accordance with their FDA-approved dosages, particularly for medications that may be diverted, or for more expensive branded medications that have bioequivalent generic forms available. For example, many payers limit daily doses of buprenorphine-naloxone to 24mg/day and closely track the amount of time that passes between refills to monitor patient adherence to a medication protocol. Payers may also limit the quantity of medications that can be filled at any one time (e.g., monthly). If a clinician prescribes more than the quantity or dose limit, then coverage for the prescription may be denied and the prescriber will need to submit an exception request.

How do I know if a patient's medication is subject to utilization management?

One way to know whether a medication is subject to utilization management is to check the formulary

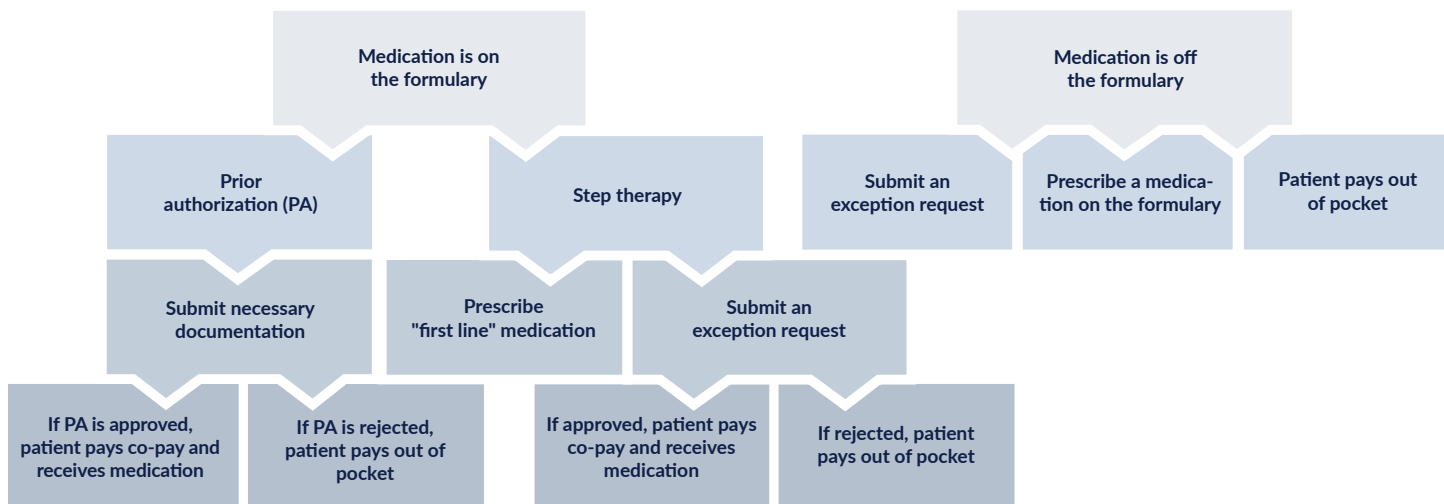
for each health plan in which you are credentialed provider. Most health plans have a provider webpage including the plan's formulary, or they provide this information to providers upon enrollment in the plan. Keep in mind, however, that health plans may change their formulary mid-year, meaning that a plan's utilization management or list of covered medications may change without warning. Keep an eye out for provider bulletins and health plan updates to stay up to date on formulary and utilization management changes.

This information may also be available at the point of care through formulary data in your electronic health record. Pharmacies, payers and electronic health records (EHRs) are moving to adopt electronic prior authorization (ePA), technology that integrates formulary data and UM requirements with practices' current electronic prescribing workflows to facilitate and expedite the approval process.

If possible, check (or have a staff member check) the prior authorization or step therapy requirements for your patient's prescription before sending the prescription to the pharmacy. Note the requirements (or have a staff member note them) in the patient's medical record. This will allow you to initiate the utilization management or exception process, if necessary, and limit care disruption for the patient.

How does utilization management work in practice?

Even if a medication is not on a health plan's formulary, it may be possible to get the medication covered. The process to follow varies depending on whether the medication is on the formulary and the type of utilization management restriction the medication is subject to.



What do I do if coverage is denied for my patient's medication?

Exception request

A prescriber may submit an exception request when a prescribed medication is either not on the health plan formulary or is subject to a step therapy requirement. When submitting an exception request, prescribers usually must justify why none of the covered or preferred medications are medically appropriate for the patient. Prescribers should expect to provide clinical justification for their decision with patient history and supporting documentation of why the requested medication is preferable to the covered alternatives. The issue may simply be that a different formulation is less expensive than the one prescribed, and a clinical rationale with supporting documentation may be required to obtain approval. Certain payers may also grant an exception to step therapy or formulary requirements if the patient is stable on a medication, allowing for maintenance of treatment for chronic conditions. This exception process can be particularly helpful when formularies change mid-plan year, allowing a patient to continue a medication despite the change.

Appeal

Under the Affordable Care Act and other federal and state rules, most patients are entitled to appeal negative prior authorization and coverage determinations. More than one level of appeal may be available to patients. The first level of appeal may be an internal appeal, in which a health plan physician conducts a document or

telephonic review. Although patients rarely appeal coverage denials, payers frequently reverse their initial coverage determinations, resulting in coverage for medications.^{vi} If an initial appeal is not successful, patients may have further appeal rights, including review of the denial of coverage by a physician external to the health plan. If an appeal review is successful, the medication or service reviewed will be covered as provided in the patient's health plan.

If a prior authorization or exception request is denied, the clinician may decide to prescribe a covered medication, or the patient may decide to pay out of pocket, or the denial may be appealed. If it is decided to appeal the decision, it is important to work quickly. Not only will this get patients their needed medications more quickly, but the timeframe in which an appeal may be initiated is limited. Upon receiving a denial, the patient should check his or her plan documents or call their plan to confirm the appeal timeframe and submit the appeal before that timeframe passes.

Expedited appeal

Under the Affordable Care Act and other rules, patients and providers may have the option for an expedited appeal of UM determinations. Many states also have state laws mandating expedited appeal timeframes shorter than 72 hours.^{vii} If an expedited appeal is clinically indicated, prescribers should request an expedited appeal of an adverse UM determination. Requesting a peer-to-peer consultation at the first possible opportunity may also speed the appeal process,

allowing you to connect with a health plan employee who is knowledgeable about patient care and better able to understand the medical necessity of the prescribed medication. Be prepared to provide all requested information to support the appeal, including copies of the medical record. For more information on appealing an insurance company decision, see <https://www.healthcare.gov/appeal-insurance-company-decision/appeals/>

What are common utilization management criteria for medications for addiction treatment?

The most frequent UM criteria implemented by health plans for any medication is to require prescribers to prescribe "to label" – meaning that the prescription falls within the bounds of use approved by the Food and Drug Administration (FDA). For example, the FDA approves dosing of buprenorphine/naloxone up to a limit of 24 mg per day to treat opioid dependence,^{viii} although some prescribers may prescribe a higher dose or use for an off-label indication. Payers frequently institute PA requirements on doses of buprenorphine/naloxone above 24mg/day, and some institute review at doses over 16mg/day. Payers frequently require prescribers to document certain clinical requirements prior to approving coverage for medications. Some common illustrative clinical requirements for medications for addiction treatment are below. Please note, of course, that individual requirements will vary depending on the individual plan's formulary and prior authorization criteria.

Common Clinical Criteria for Medications for Addiction Treatment

Medication	Clinical requirements
Varenicline (e.g., Chantix®)	<ul style="list-style-type: none">• History of failure, contraindication, or intolerance to nicotine patches, gum, or lozenges• History of failure, contraindication, or intolerance for bupropion
Nicotrol® NS or Nicotrol®, Inhaler	<ul style="list-style-type: none">• History of failure, contraindication, or intolerance to nicotine patches, gum, or lozenges• History of failure, contraindication, or intolerance for bupropion
Acamprosate (e.g., Campral®)	<ul style="list-style-type: none">• Medication is prescribed as part of a comprehensive psychosocial treatment program• Abstinence from alcohol at treatment initiation• No severe renal impairment• Inadequate treatment response, intolerance, or contraindication to naltrexone
Buprenorphine/naloxone (e.g., Suboxone®, Zubsolv®, Bunavail®)	<ul style="list-style-type: none">• Medication is used as part of a complete psychosocial treatment program, including behavioral therapies• Prescriber agrees not to prescribe other opioids and patient agrees not to take other opioids• Dose does not exceed 16-24mg/day
Buprenorphine mono-product (e.g., Subutex)	<ul style="list-style-type: none">• Patient is pregnant or breastfeeding• Patient has experienced a documented serious allergic reaction to the buprenorphine/naloxone combination product• Medication is being used for induction therapy

What state and federal laws/policies should I be aware of?

Federal/state mental health and substance use disorder parity requirements

Under federal and state parity laws, certain health plans are required to provide mental health and substance use disorder treatment benefits that are subject to no less favorable limitations than those applied to benefits for physical health conditions, such as heart disease or diabetes. These laws may extend to how health plans provide pharmacy benefits and decide which medications will be covered, meaning that health plans may only use factors unrelated to whether the medication is generally prescribed for a mental health or substance use disorder when determining coverage and cost-sharing requirements for patients. If you or your patient suspects that a health plan is in violation of state or federal parity requirements, you or your patient may file a complaint with the appropriate regulatory body (i.e., your state insurance commissioner, the U.S. Department of Labor or the U.S. Department of Health and Human Services, depending on the type of insurance coverage you have).^{ix}

Removal of prior authorization entirely

In response to the opioid overdose epidemic, several states have enacted

laws prohibiting prior authorization on medications for addiction treatment or minimizing the burden of step therapy protocols. It is important to note, however, that these state laws only apply to certain health plans – meaning that even if such a law is passed, certain patients will still need assistance with prior authorization and other UM requirements. Many state Medicaid programs have also eliminated prior authorization on certain medications for addiction treatment. Check to see if your state has implemented limitations on prior authorization and step therapy to better understand how they may impact your practice.^x

In April 2018, the Centers for Medicare and Medicaid Services (CMS) announced that it would not approve Medicare Part D formularies that required prior authorization for buprenorphine products more frequently than once a year.^{xi}

Unified Preferred Drug Lists for Medicaid programs

Most states contract with managed care organizations to administer their Medicaid benefits. As a result, formularies can vary widely across Medicaid managed care plans. To create more consistency in the medication benefits provided to Medicaid beneficiaries, many states are creating unified preferred drug lists that apply to all managed care plans. Contact your state Medicaid agency to learn whether your state uses a unified preferred drug list.^{xii}

How can I minimize care disruptions due to utilization management requirements?

Create standard processes and documentation standards

Utilization management requests can be disruptive, particularly when they require response outside of the regular patient care workflow. To the extent possible, prescribers should anticipate the need to meet utilization management requirements and build processes into standard workflows to minimize the disruption and time needed to respond to requests. It will always be more time-efficient for a clinician to prescribe a preferred formulary agent at an FDA-approved dosage for an approved condition, if that is an equivalent clinical choice. Although each payer establishes its own UM standards, requirements for each medication are often similar across plans. As a result, prescribers can plan for prior authorization and other UM events by creating consistent, thorough documentation in the patient's medical record. Readily available information will save time in completing UM requests and help patients get their medications faster. Additionally, some states have collaborated with local payers to create standardized prior authorization request forms to simplify the prior authorization process.^{xiii} Prescribers can utilize standardized prior authorization forms where possible to minimize the need to tailor individual responses.



Choose your prior authorization method wisely

Prior authorization can be obtained by phone, fax, secure email, or electronically. Each method for submitting prior authorization and other information to health plans has

benefits and drawbacks.^{xiv} Prescribers should note, however, that many states mandate the use of electronic prior authorization (ePA) in certain circumstances.^{xv} Beginning no later than January 1, 2021, Medicare Part

D plans will be required to accept ePA requests and send ePA responses.^{xvi} You can use the below table, provided courtesy of the American Medical Association, to gain a better understanding of each method.^{xvii}

Pros and Cons of PA Methods

Method	Pros	Cons
Standard electronic transaction	<ul style="list-style-type: none"> • Electronic PA (ePA) standard developed by National Council for Prescription Drug Programs integrates with EHR and e-prescribing workflow • Alerts the prescriber to PA requirement before issuing the prescription, allowing PA to be completed before prescription is sent to pharmacy and reducing medication nonadherence • PA questions are presented onscreen for prescriber or staff • Conditional logic ensures that physician only answers relevant questions • Average approval time significantly reduced • PAs can be electronically appealed and cancelled 	<ul style="list-style-type: none"> • Pharmacy ePA solutions integrated into EHR workflow are not yet widely available across vendors • PA requirement is not always known at the point of prescribing due to inaccuracy/incompleteness of EHR drug formulary data • Response may not be in real time due to manual health plan processing and review <p>TIPS: Ask your EHR vendor about ePA capability—and learn more about ePA through an educational video series.</p>
Payer portal	<ul style="list-style-type: none"> • All required information presented in one place • Often less time consuming than manual processes (fax/phone) • If drug PA approval is immediate, prescription can be sent to pharmacy and filled without delay 	<ul style="list-style-type: none"> • Outside of EHR workflow • Requires separate login/password for each health plan website • Information from EHR must be re-typed onto web forms <p>TIP: Keep a list of health plan portal logins and passwords (store in secured place).</p>

Continued >

Pros and Cons of PA Methods

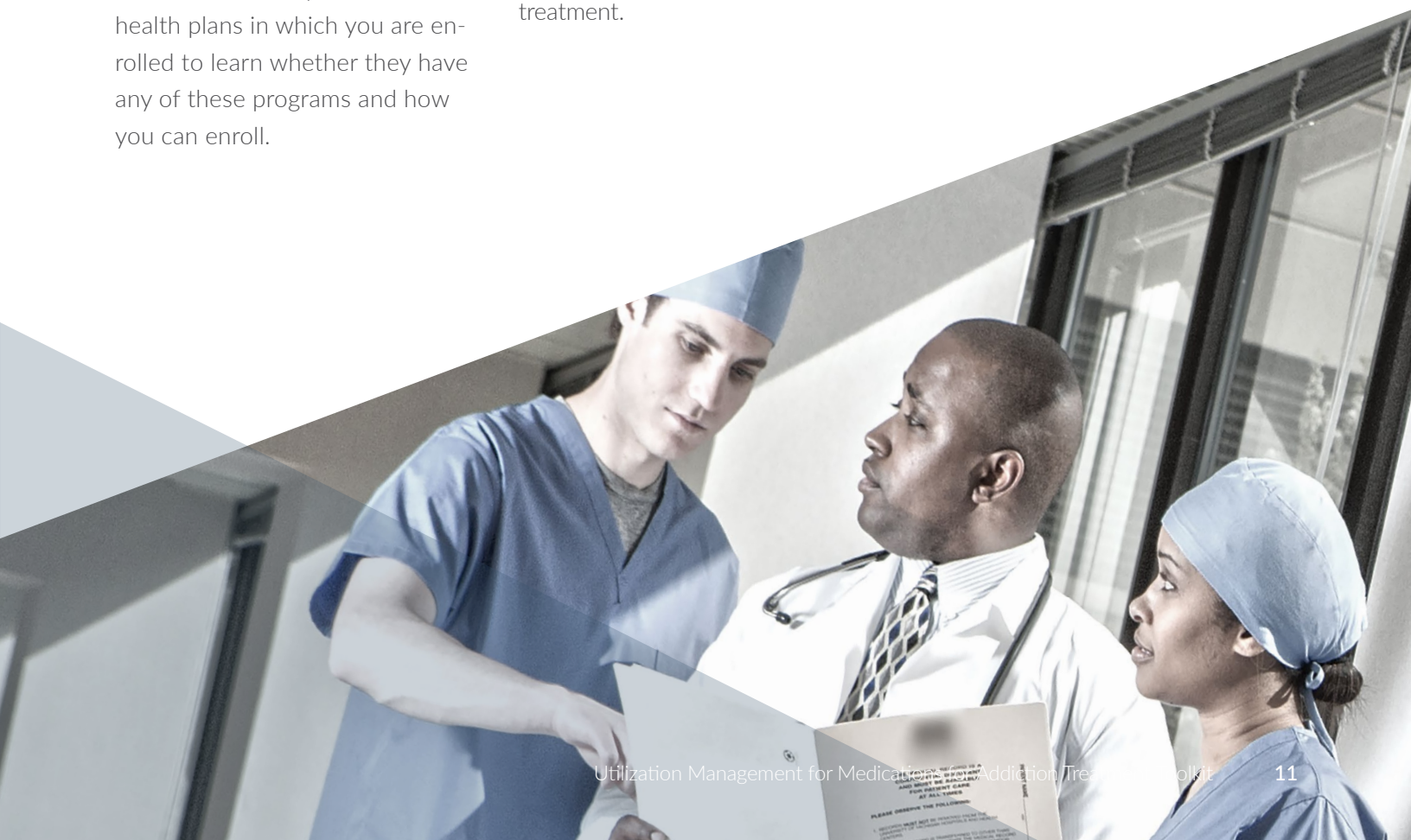
Method	Pros	Cons
Fax	<ul style="list-style-type: none">• Widely available method of PA submission• Library of payer forms can be developed	<ul style="list-style-type: none">• Forms must be filled out by hand• Potential confusion in selecting correct/current PA form• Outside of EHR workflow• Lack of security encryption• No feedback loop; practice may not be informed when drug PA is approved <p>TIP: Keep all documents and records regarding faxed PA documents, including date and time stamps from fax machine</p>
Telephone	<ul style="list-style-type: none">• In many cases, all information can be reported verbally at one time• Reduce or eliminate delay in receiving approval• Appeal can be begun immediately, if needed	<ul style="list-style-type: none">• Long hold times frequent• Interrupts regular EHR workflow• Transaction is not automatically documented in the EHR• May be difficult to later “prove” conversation with plan• May still require supporting documentation to be faxed• Approval must be relayed to the pharmacy <p>TIP: Keep a record of the first and last name of the person spoken to, date, and time in case necessary for appeal.</p>

Ask health plans if there are alternatives

In response to concerns about the administrative burden, some payers have created options for enrolled providers to avoid some UM requirements. Some states^{xvii} and commercial insurers^{xix} are implementing “gold card” programs that allow providers to bypass prior authorization or other UM requirements if they meet certain criteria, such as a consistently high prior authorization approval rate. Other payers permit providers to skip prior authorization or other UM requirements if they use payer-approved, clinically-developed appropriate use criteria or clinical decision supports.^{xx} Such programs are not yet prevalent, but clinician and patient advocacy groups have called on insurers to implement them more broadly.^{xxi} Contact the health plans in which you are enrolled to learn whether they have any of these programs and how you can enroll.

Improving the prior authorization process

Prior authorization is not just an administrative burden – it has real ramifications for patient care. Particularly for patients initiating treatment for addiction, prior authorization denials can lead to delays that result in patients abandoning treatment altogether. Even if you are a provider that operates a self-pay practice, your patients often still must bear the cost of co-pays, co-insurance, or the full costs of their medications. For that reason, prescribers should be aware of preferred formularies and prior authorization requirements for the health plans most often seen in their practice. Informing their practices and patients that prior authorization may be needed should decrease the barrier to treatment.



Example of an Inefficient Prior Authorization process

Patient Visit

- The prescriber sees a patient and determines that a prescription for a medication for addiction treatment is appropriate.

Prescription Sent to Pharmacy

- The prescriber sends the prescription to the pharmacy without checking the formulary.

Pharmacy Submits for Coverage

- The pharmacy submits the prescription for coverage by the patient's health plan.

Coverage denial

- The health plan denies coverage for the prescription, having not received the necessary prior authorization documentation.

Patient arrives at the pharmacy

- The patient arrives to collect their medication but learns that it won't be covered by their health plan.
- The patient either pays out of pocket, returns to the pharmacy after the prior authorization process is complete, or abandons treatment.

Pharmacy alerts the prescriber

- The pharmacy reached out by phone or email to alert the prescriber that the prescription is subject to prior authorization and won't be covered by the patient's health plan without additional documentation.

Prescriber submits prior authorization request documentation

- Outside of the patient work flow, the prescriber must open a patient's file, look up the necessary documentation, and submit the prior authorization request to the patient's health plan.

Health plan approves coverage

- Having received the necessary documentation, the health plan approves coverage for the patient's medication.

Patient receives medication

- Assuming the patient has not paid out of pocket or abandoned treatment, the patient picks up their prescription.



Example of an Efficient Prior Authorization Process

Patient Visit

- The prescriber sees a patient and determines that a prescription for a medication for addiction treatment is appropriate.
- The prescriber has access to the formulary of the patient's health plan and selects a medication that is available without prior authorization or prepares to submit the prior authorization request.

Prescriber Submits Request

- The prescriber submits an electronic prior authorization request with the necessary documentation prior to sending the prescription to the pharmacy.

Payer Reviews

- Having all needed documentation, the health plan reviews the prior authorization request and alerts the prescriber that they will cover the medication.

Pharmacy Dispenses

- The prescriber sends the approved prescription to the pharmacy .
- The pharmacy submits the prescription to the health plan for coverage under the patient's health plan.
- Pharmacy dispenses the medication to the patient.

Where can I learn more?

a. American Medical Association: Tips to Help Physicians Reduce the Prior Authorization Burden in their Practice: https://www.ama-assn.org/sites/ama-assn.org/files/corp/media-browser/premium/psa/prior-authorization-tips_0.pdf

b. Beating the Prior Authorization Blues: <https://www.aafp.org/fpm/2016/0900/p15.html>

c. Medicaid and CHIP Payment and Access Commission (MACPAC): Report to Congress: Utilization Management of Medication-Assisted Treatment in Medicaid: <https://www.macpac.gov/wp-content/uploads/2019/10/Report-to-Congress-Utilization-Management-of-Medication-Assisted-Treatment-in-Medicaid.pdf>

d. Healthcare.gov: How to appeal an insurance company decision: <https://www.healthcare.gov/appeal-insurance-company-decision/appeals/>

e. The Kennedy Forum: A Consumer Guide to Drug Formularies: Understanding the Fundamentals of Behavioral Health Medications: https://www.thekennedyforum.org/app/uploads/2017/09/170824-KF-Consumer-Guide-Drug-Form-Issue-Brief-0817_4.

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- ^{vi} Kaiser Family Foundation. Claims Denials and Appeals in ACA Marketplace Plans. Available at: <https://www.kff.org/private-insurance/issue-brief/claims-denials-and-appeals-in-aca-marketplace-plans/>.
- ^{vii} American Medical Association. 2018 Prior Authorization State Law Chart. Available at: <https://www.ama-assn.org/media/22571/download>.
- ^{viii} Suboxone Drug Label. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2010/022410s000lbl.pdf.
- ^{ix} American Psychiatric Association, How to File a Complaint. Available at: <https://www.psychiatry.org/psychiatrists/practice/parity>.
- ^x See, e.g., Legal Action Center. State Medicaid Programs Should Follow the "Medicare Model." Available at: <https://lac.org/wp-content/uploads/2019/07/access-to-meds-in-medicaid-eweber-FINAL-070919.pdf>; National Psoriasis Foundation, Step Therapy Legislation by State. Available at: <http://www.steptherapy.com/step-therapy-legislation-by-state/>.
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- ^{xiv} NCPDP SCRIPT Standard Supports Electronic Prior Authorization (ePA) Fact Sheet. Available at: https://www.ncdp.org/NCPDP/media/pdf/NCPDP_ePA_Fact_Sheet.doc.
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