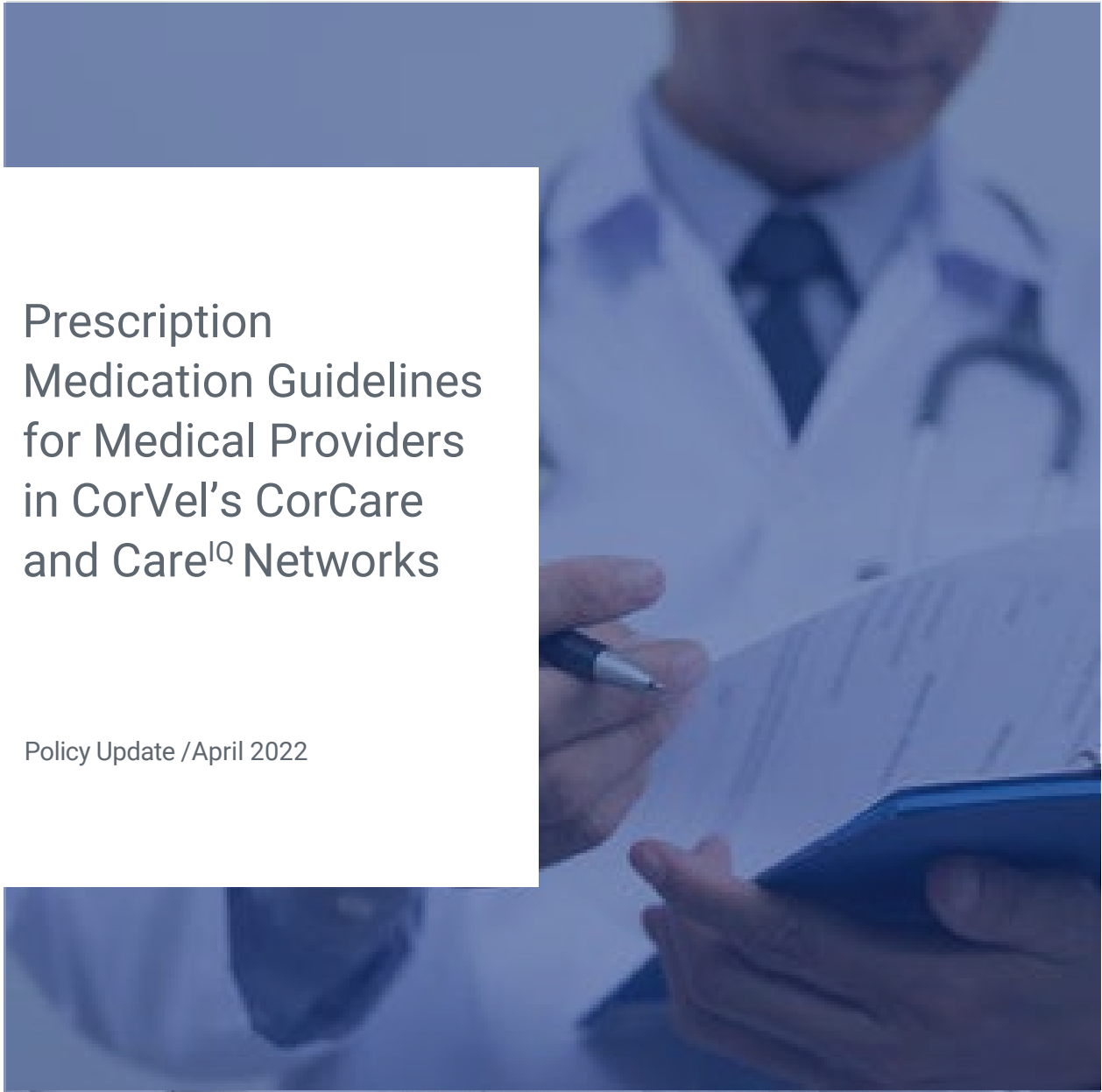




Prescription Medication Guidelines for Medical Providers in CorVel's CorCare and Care^{IQ} Networks

Policy Update / April 2022



PATIENT HEALTH AND SAFETY GUIDELINES – PRESCRIPTION MEDICATIONS

In connection with the delivery of health care, CorVel, its customer employers and payers, and medical providers treating covered claimants are committed to: maximizing safety, improving quality, enforcing state formulary and treatment guidelines, expediting return to work, and delivering cost-effective care. Prescription medications provide many benefits and are an important element of patient care; however, prescribers and patients face many challenges in the safe and effective delivery and use of medications.

According to the National Center of Health Statistics (NCHS) at the Centers for Disease Control and Prevention (CDC), in 2020 approximately 92,000 people in the United States died from drug-related overdoses. This was a significant increase from about 70,000 deaths in 2019. Of those 92,000 deaths in 2020, approximately 68,000 of them were opioid-involved overdose deaths. This was also a significant increase from 47,000 opioid-related overdose deaths in 2018. The previous figure also includes illicit opioids such as heroin. While the two previous categories have been vastly increasing, the number of people in the United States dying from prescription opioid overdoses has been decreasing every year, while slightly increasing from 14,000 in 2019 to 16,000 in 2020. It is possible that the COVID-19 pandemic has contributed to the recent uptick in deaths.

Despite the recent reversal in the trend of decreasing prescription opioid-related overdose deaths, there continues to be positive movement in the opioid crisis. Examples of positive aspects have been the overall reduction in opioid prescriptions numbers, as well as reductions in the average day's supply of prescribed opioid medications. Much of this can be contributed to legislative action to place quantity limits on opioids that can be prescribed/dispensed, as well as a focus on using opioid alternatives for pain management.

Hundreds of thousands more patients on prescription drugs will suffer a lifetime of health problems stemming from unforeseen drug interactions, allergic reactions, over-use, and dependent and addictive behaviors. This epidemic spans all socioeconomic classes and communities and includes patients with workers' compensation and automobile injuries.

Prescribing and dispensing medications safely is critically important. CorVel believes that managing prescription medications retrospectively after they are dispensed, presents unacceptable levels of risk to patient safety and health when compared with managing medications prospectively, before dispensing, through an integrated pharmacy database and drug utilization review.

- CorVel defines an *integrated* pharmacy dataset as historical pharmacy data that transcends the current episode of care and prescriber, including prescriptions from other prescribers.
- CorVel defines drug utilization review as an algorithm applied before dispensing that considers the presenting medication's safety and efficacy in context with other medications that have been dispensed. In addition, the algorithm includes applicable protocols and guidelines based on the medication and specific patient characteristics such as allergies.

To mitigate these risks and improve patient safety, quality, and cost-effectiveness relative to prescription medications, CorVel, as part of our Utilization Management Program, has adopted and is publishing our Prescription Medication Guidelines to help prescribers make the best, safest, and cost-effective decisions when treating covered patients. We expect all network medical providers prescribing medications to apply the following seven (7) guidelines summarized below and detailed on the following pages of this Policy Update:

CorVel’s Seven Prescription Medication Guidelines for Contracted Providers (Summary)

- 1) Direct all patients with prescriptions to fill medications through your patients’ own local retail pharmacies unless the prescriber or pharmacy vendor accesses an integrated pharmacy dataset and drug utilization review program prior to dispensing, or a local retail pharmacy is not available. You are required to document exceptions.
- 2) Do not dispense prescription medications in office unless the prescriber’s office accesses an integrated pharmacy dataset and drug utilization review program, prior to dispensing, or a local retail pharmacy is not available. You are required to document exceptions.
- 3) Support scripts for oral and topical compounded medications with a Statement/Letter of Medical Necessity detailing the medical rationale and why FDA-approved, non-compounded medications or over-the-counter remedies were not prescribed. Compounded medications should be dispensed by compounding pharmacies registered with the FDA as “Outsourcers” per the Federal Drug Quality and Security Act of 2013. This does not apply to compound medications mixed by prescribers in their own offices, including medications administered through an intravenous infusion, vaccine, and/or joint injection. You are required to document exceptions.
- 4) Support state formulary and treatment guidelines including opioid day supply regulations specific to each state jurisdiction. Reference formulary and prescription protocols, including prior authorization and request for authorization processes. Adhere to guidelines when possible and be prepared to support non-formulary recommendations. Promptly reply to the letter of medical necessity requests and actively participate in Utilization Reviews.
- 5) Educate patients on the efficacy of generic medications and when appropriate, rebut marketing claims promoted by manufacturers of branded medications unless the generic medications are contraindicated, ineffective, and not appropriate for your patient. You are required to document exceptions.
- 6) Educate patients on the efficacy of Step Therapy and Therapeutic Exchange programs, when appropriate and upon the pharmacy’s request, and consider exchanging the indicated drug unless the Step Therapy/Therapeutic Exchange drug is contraindicated, ineffective, and not appropriate for your patient. You are required to document exceptions.
- 7) Follow and adhere to applicable guidelines when prescribing opioids for patients with pain. No exceptions.

Because of the safety and health risks associated with prescription medications, pharmacy management is a cornerstone of quality patient care and CorVel’s Utilization Management Program. As a contracted provider through the CorCare and/or Care^{IQ} networks, you are obligated to follow CorVel’s Utilization Management Program, including these Prescription Medication Guidelines, and promote patient safety, health, and cost-effective care.

1

Practice: Directing or referring patients to unmanaged dispensing sources

Guideline: Prescribers must support safe dispensing through prospective management by instructing patients to fill all prescriptions for medications at local retail pharmacies, if available.

Managing prescription medications prospectively through an integrated pharmacy database and drug utilization review embedded before the medications are dispensed helps to ensure a high level of patient safety. Scripts filled in-office by prescribers or by pharmacies with no access to these safety tools are not as safe as scripts filled by pharmacies with these tools. Risks include exposure to drug-to-drug interactions, allergic reactions, suprathereapeutic or subtherapeutic dosages, duplicate therapies, and opioid abuse and diversion.

CorVel expects prescribers to promote a high level of safety by instructing patients to fill prescriptions at the patient’s own neighborhood pharmacy, or any retail pharmacy, utilizing an integrated pharmacy database and drug utilization review. Pharmacy Benefits Management (PBM) Programs add an additional layer of safety and prescribers should promote the use, if applicable, when filling and re-filling prescriptions.

Most often, the patient’s retail pharmacy will have the patient’s complete drug history to identify harmful interactions, allergic reactions, duplicate therapies, and multiple prescribers, increasing patient safety. Moreover, the retail pharmacy most likely will follow industry-standard practice for work comp and auto claims and process and dispense the medication/s expeditiously **with no cost or unnecessary delay to the patient** through an assignment/third party process, or if identified, through a PBM.

Exceptions – CorVel expects prescribers to document exceptions in the medical record:

- 1) Prescribers who access an integrated pharmacy dataset and drug utilization review program prior to dispensing; or
 - 2) A local retail pharmacy is not available.
- CorVel defines an integrated pharmacy dataset as historical pharmacy data that transcends the current episode of care and prescriber, including prescriptions from other prescribers.
 - CorVel defines drug utilization review as an algorithm applied before dispensing that considers the presenting medication’s safety and efficacy in context with other medications that have been dispensed. In addition, the algorithm includes applicable protocols and guidelines based on the medication and specific patient characteristics such as allergies.

Guideline #1 covers all prescriptions, including medications dispensed in-office, oral and topical compounded medications, and medications dispensed through “work comp” pharmacies that do not access integrated pharmacy data and drug utilization review and deliver medications to patients’ homes. If your patient prefers delivery, safer options from mail-order pharmacies with access to integrated pharmacy data and drug utilization review are available through your patient’s payer (TPA/employer/insurance company).

2

Practice: Prescriber dispensing prescription medications in-office

Guideline: Prescribers are not allowed to dispense medications in-office.

Prescribers who dispense medications, including oral and topical compound medications, in-office with no access to an integrated pharmacy database and drug utilization review, and inadequate warning labels put their patients and the public at risk for drug-to-drug interactions, allergic reactions, suprathereapeutic or subtherapeutic dosages, duplicate therapies, and opioid abuse and diversion. This risk is unacceptable when the same medications are readily available from nearby retail pharmacies that typically dispense medications prescribed for work comp and auto claims at no cost or unnecessary delay to the patient through either a PBM or an assignment/third party process.

- CorVel defines an *integrated* pharmacy dataset as historical pharmacy data that transcends the current episode of care and prescriber, including prescriptions from other prescribers.
- CorVel defines drug utilization review as an algorithm applied before dispensing that considers the presenting medication’s safety and efficacy in context with other medications that have been dispensed. In addition, the algorithm includes applicable protocols and guidelines based on the medication and specific patient characteristics such as allergies.

Recent studies suggest that the outcomes of claims with prescriber dispensed medications are worse than similar claims with no prescriber dispensing. One such study from the California Workers’ Compensation Claims Institute, published in February 2013, finds that claims with prescriber-dispensed medications do not return to work as quickly as similar claims without prescriber-dispensed medications, specifically claim with prescriber dispensing incur 9% more lost-time days. In addition, total claims costs are higher: claims with prescriber dispensing incur 17% higher medical benefit costs and 13% higher indemnity costs. Link to study: http://www.cwci.org/press_release.html?id=318.

Exceptions - CorVel expects prescribers to document exceptions in the medical record:

- a) Prescribers who access an integrated pharmacy dataset and drug utilization review program prior to dispensing; or
- b) A local retail pharmacy is not available; or
- c) Prescribers administering intravenous drug infusions, vaccines, and/or joint injections using ingredients that were not procured from compounding pharmacies.

*These exceptions do not apply if Federal or State Rules or Regulations mandate that physicians must check an integrated pharmacy database prior to dispensing a legend medication.

3

Practice: Medications that Require Compounding

Guideline: "Compounding" is defined as the preparation, mixing, assembling, packaging, or labeling of a drug. Compounded medications include but are not limited to, medication kits that are self-contained and require the provider or patient to combine/mix the products. Documentation supporting the Medical Necessity of oral & topical compounds and why non-compounded meds and over-the-counter remedies were not prescribed is required.

Medical Necessity

CorVel values a "risk ladder" approach to pharmacotherapy and appreciates the consideration of non-habit-forming pharmacotherapy over high risk and addictive pain medications, however, oral compounds and compounded creams, lotions, and ointments do not have appropriate and documented clinical support and lack FDA approval. At times, topical medication therapy is appropriate and may be considered the most effective treatment for a patient's condition. Compounded topical therapy is effective. CorVel requires practitioners prescribing compounded topical therapies to utilize pharmacies that are in-network. If a prescriber is unsure or unaware of current in-network compounding pharmacies, CorVel may provide options for compounded topical prescription fulfillment. Prescribers must document the medical necessity of these compounds and state why FDA-approved, non-compounded medications and over-the-counter remedies were not prescribed. No exceptions.

Cost-Effective Therapy

CorVel encourages practitioners to utilize and prescribe OVER-THE-COUNTER topical medications as step therapy when topicals involving ingredients found in these products are available. These ingredients include but are not limited to; capsaicin, menthol, lidocaine, and diclofenac 1%. Examples of these manufactured products include but are not limited to: Icy Hot, BioFreeze, Voltaren 1% Gel, SalonPas, and Aspercreme. CorVel will honor prescriptions written for these OTCs when prescribed for a related injury.

Patient Safety

The Federal Drug Administration (FDA) has expressed concern regarding compound medications. The FDA's concerns include (a) compounding drugs prior to receipt of a valid prescription because this raises inferences about whether these are tailored to the presenting patient's needs and being prescribed often enough to suggest FDA approval should be required, and (b) compounding drugs that are essentially copies of commercially available products because it is questionable whether there is any need to compound these agents.

For oral and topical compounds that are Medically Necessary, prescribers should refer to compounding pharmacies registered as "Outsourcers" per the FDA and are in good standing.

Exception - CorVel expects compounding pharmacies that are not registered as “outsourcers” or are not in good standing with the FDA to submit a Letter of Attestation stating that:

- a) Compounding pharmacy mixes the ingredients specifically in limited quantities before the unsolicited receipt of a prescriber’s prescription order and does not prepare compounds in bulk thereby more properly designating compounds as a manufactured drug requiring FDA regulation and approval; AND
- b) Compounded medications are not essentially a copy of a product that is commercially available and thereby subject to FDA regulation and approval.

Itemization Required for Billing

Bills for oral and compounded topical gels, creams, and ointments must be itemized by ingredients and quantities of each ingredient, including NDCs (national drug codes). No Exceptions.

Injectable Compounds

CorVel follows Federal Drug Quality and Security Act directives and requires pharmacies supplying compounded medications to be registered as outsourcers with the FDA. Bills for medications supplied from compounding pharmacies that are not registered as outsourcers with the FDA will be denied.

Exceptions – CorVel expects prescribers to document exceptions in the medical record:

- 1) In this section the term “compounding” does not include mixing, reconstituting, or other such acts that are performed in accordance with directions contained in approved labeling provided by the product's manufacturer and other manufacturer directions consistent with that labeling.
- 2) Injectable compounds created for office use by licensed health care practitioners using ingredients (other than bulk drug substances) that comply with the standards of an applicable United States Pharmacopoeia or National Formulary monograph, if a monograph exists, and the United States Pharmacopoeia chapter on pharmacy compounding.

4

Practice: Supporting state formulary and medical treatment guidelines

Guideline: Adhere to formulary guidelines and be prepared to support non-formulary recommendations.

CorVel supports state and federal prescribing guidelines, including all state workers' compensation regulations. Reference formulary and prescription protocols, including prior authorization and request for authorization processes specific to most states. Adhere to guidelines when possible and be prepared to support non-formulary recommendations. Promptly reply to requests for Letters of Medical Necessity and participate in Utilization Reviews when requested.

CorVel enforces pre-authorization and utilization review processes in all states with these outlined requirements. If formulary medication is not effective or appropriate for the patient, a pre-authorization process may be required.

5

Practice: Educating patients on the efficacy of generic medications

Guideline: Prescribers must educate patients on the efficacy of generic medications when clinically appropriate.

Marketing campaigns across all media, especially print, television, and radio, are designed to influence consumers to “ask their doctor” for specific brand drugs. CorVel promotes patient education and choice, and therefore expects prescribers, when appropriate and warranted, to educate their patients on the efficacy of generic options and rebut false expectations of brand superiority driven by consumer marketing and other influences.

Generic medications that are not contraindicated for your patient are as safe and effective in treating underlying symptoms and conditions for which they are prescribed as the corresponding brand drugs. The Food and Drug Administration (FDA) defines generic drugs as “a medication created to be the same as an already marketed brand-name drug in dosage form, safety, strength, route of administration, quality, performance characteristics, and intended use. These similarities help to demonstrate bioequivalence, which means that **a generic medicine works in the same way and provides the same clinical benefit as the brand-name medicine.**” CorVel expects prescribers to promote cost-effective care, educate their patients, and prescribe and support generics as appropriate.

Exception - CorVel expects prescribers to document exceptions in the medical record: Generic versions of brand drugs that are contraindicated or not effective for your patient.

6

Practice: Educating patients on the efficacy of Step Therapy and Therapeutic Exchange

Guideline: Prescribers must educate patients on the efficacy of Step Therapy and Therapeutic Exchange, and when clinically appropriate and upon the pharmacy’s request, apply the requisite Step Therapy protocols or Therapeutic Exchange.

CorVel promotes patient education and choice, and therefore expects prescribing providers, when appropriate and warranted, to educate their patients on the efficacy of Step Therapy and Therapeutic Exchange. When a dispensing pharmacist or PBM staff requests Step Therapy or Therapeutic Exchange for an indicated drug, prescribing providers are expected to support the alternate drug therapy regime for a fixed period based on established protocol before stepping the patient into the indicated drug.

An alternate drug therapy regime that is not contraindicated for your patient may be as safe or safer, less expensive, and as effective in treating the underlying symptoms and conditions for which they are taken as the prescribed and indicated drug. A combination drug such as Duexis an example: prescribers are expected to approve the exchange of ibuprofen and famotidine (generic Pepcid) for Duexis. CorVel expects prescribers to promote cost-effective care, educate their patients, and support and apply Step Therapy and Therapeutic Exchange as appropriate. Another common scenario where this principle can be applied is with regards to “Private Label Topical Analgesic” medications for pain. Private label topicals are not approved by the FDA, and lack in clinical safety and efficacy data to support their use. An example is Lidopro patches or cream. They contain combinations of active ingredients such as Lidocaine, Menthol, and Methyl Salicylate. These can easily be substituted with over-the-counter products that contain the same active ingredients, and are more easily accessible for use.

Exception – CorVel expects prescribers to document exceptions in the medical record:

Step Therapy Protocols or Therapeutic Exchanges that are contraindicated or not effective for your patient.

7

Practice: Prescribing opioids for pain without adhering to applicable guidelines

Guideline: Prescribers must follow and adhere to applicable guidelines when prescribing opioid therapy to pain patients.

The CDC reports a substantial increase in the availability and misuse of opioids over the last 10- 15 years, with more than 15,000 fatal overdoses reported in 2015. That number had declined to about 14,000 in 2019 but climbed back up again to over 16,000 in 2020. Opioids are powerful medications to treat pain but are addictive and today are often over-prescribed or prescribed inappropriately. Even with widespread national attention, on this issue and documented reductions in prescriptions, medical providers prescribe opioids to over 50% of patients covered under workers’ compensation; and providers continue to prescribe opioids to over 25% of their work comp patients 30 days after the initial prescription.

Following an accepted and effective opioid therapy guideline is critically important to keeping patients safe. CorVel expects prescribers to adhere to an appropriate guideline applicable to their specialty and state when prescribing opioids for patients suffering from pain due to their compensable injuries. It is expected that providers address standard practices of opioid safety as documented in their medical notes; examples include (not an exhaustive list) regular urine drug screen results, maintaining signed pain contracts on file, and regular Prescription Drug Monitoring Program (PDMP) checks. Other examples include: documenting the trial and failure of alternate pain therapies...including pharmacological and non-pharmacological modalities and documenting the continuously updated opioid treatment plan (to note efficacy of regimen and if weaning will be addressed). No Exceptions. In a growing number of states, guidelines are mandatory.

Below are links to opioid guidelines for your reference. State regulations may apply. In addition, CorVel expects prescribers to document relative to function, improved functioning, and pain.

Links of Guidelines:

- The CDC Guideline for Prescribing Opioids for Chronic Pain – United States 2016
<https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm>
- <http://odg-disability.com/orderformtrial.htm>
 - Work Loss Data Institute’s Official Disability Guidelines 30-day trial to review, evaluate and use ODG.
 - <http://www.guideline.gov/content.aspx?id=33188&search=odg> is a direct link to the chronic pain guideline
 - <http://www.guidelines.gov/search/search.aspx?term=odg> is an abbreviated version of ODG from Guidelines.gov and is available at no charge.
- IAIABC Guideline – <http://www.iaibc.org/i4a/forms/index.cfm?id=94>
- The State of Washington (the first state mandated opioid guideline)
<http://www.guideline.gov/content.aspx?id=23792&search=opioid>