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Tennessee Workers' Compensation Drug Formulary FAQ

Since notice of adoption, the Tennessee Bureau of Workers' Compensation has received several questions from various parties on the application of the Tennessee Drug Formulary rules. To assist, below are responses to some of those questions. This document is NOT INTENDED to replace the rules which can be found at:

<http://share.tn.gov/sos/rules/0800/0800-02/0800-02-25.20160228.pdf>. The Drug Formulary is part of existing Medical Treatment Guidelines.

Important Formulary Dates

Q: What is the effective date of the drug formulary?

A: The drug formulary rules are effective as of February 28th, 2016.

Q: What are application dates of the drug formulary?

A: The drug formulary guidelines will apply to all **new** prescriptions written after January 1, 2016. It will also apply to all **refills of prescriptions written** prior to January 1, 2016, but at a later date, depending on the specifics of the prescribed medications.

Q: What does it mean for a particular prescription medication?

A: All drugs dispensed after August 28, 2016 (with a prescription that was written **after** January 1, 2016) will be subject to drug formulary guidelines. There is a further notification period for dispensed **refills** until February 28, 2017. See below.

Q: What is the definition of a refill?

A: An initial prescription written before January 1, 2016 with the following characteristics:

1. Same medication
2. Same dose or strength
3. Same quantity
4. Same frequency
5. Same instructions

It should be noted that Federal and Tennessee prescribing laws and rules limit the dispensing of controlled substances to certain monthly supplies and post-dated prescriptions. Those further prescriptions are considered refills if characteristics of the prescription otherwise match those listed above.

Q: What does this mean for older claims and/or long standing prescription medications?

A: For prescriptions that are refills, as defined above, the date of the claim does not matter but long standing prescriptions are subject to separate time frames. For any refills of a drug being used or prescribed before January 1, 2016, the drug formulary will apply to these prescriptions on or after February 28, 2017.

It is not likely that many of the patients taking long acting opioids will be able to be completely weaned. It is suggested that significant latitude be given to the treating physician with these patients. Proactive review and ongoing, constructive communication with the physician is advised. The Department of Health has published guidelines giving further guidance to patients and physicians. See:

<http://www.tn.gov/assets/entities/health/attachments/ChronicPainGuidelines.pdf>.

Q: How about newer claims?

A: Attention should be paid to individuals first receiving these medications, particularly “N” medications.

Using the treatment guidelines to evaluate the need for, and evidence supporting the results of these medications should be an important step in future use and aid in prevention of abuse. Alternative therapies have a significant role to play in improving outcomes and fostering return-to-work.

Q: Why do claims have a bifurcated application date for the drug formulary regulations?

A: To allow prescribers and injured workers a longer window in order to discuss and consider alternative options for ongoing and long term treatments.

Q: If the medication was dispensed previously, is there a time frame on the look back as to when it was dispensed previously?

A: No. The statement in the rules only talks about allowance for 12 months going forward, not how far back to look to determine if the drug should be allowed. The intent of the rules is to not cut injured workers off from medications they are already using.

Notification Period

Q: What was the period between January 1, 2016 and August 28, 2016 supposed to do?

A: This was to allow patients, pharmacists and doctors time to review and understand formulary processes. During that period, there were to be no denials or other changes in how the present system worked. Patients and physicians began to receive letters from PBMs or insurers concerning those medications that would require prior approval after August 28, 2016 (for new prescriptions) and after February 28, 2017 (for refills of old prescriptions).

Q: The formulary process seems so complicated. Why?

A: This is not any different than the processes already used by commercial insurance formularies and TennCare. If the physician writes to allow substitution, then the process for workers’ compensation prescriptions should be as seamless and smooth as for any non-Worker’s Compensation prescription. Coverage limits in Workers’ Compensation are different than other formularies.

Prior Approval

Q: What is the prior approval (PA) process?

A: It is the process that the insurer uses when a prescription is presented to a pharmacy to be paid under a claim for Workers' Compensation.

1. Is the medication appropriate for the injury being covered?
2. Is it first line or second line treatment?
3. Does the medication actually require prior approval or is it a "Y" drug in the formulary?
4. Is it a compound or topical?
5. Is there an acceptable generic or equivalent "Y" medication that is allowed by the prescription?

This process is sometimes handled through a pharmacy benefits manager or other intermediary and is usually fairly rapid. Denials at this stage may be related to other factors such as the claim has not been accepted by the insurer.

Q: What happens when you do not receive prior approval?

A: Ask the pharmacist if he/she can find out the reason. Get the contact telephone numbers for the PBM or the insurer (adjuster) and get all this information to discuss with your prescriber. Supplemental explanations from your prescriber by letter or telephone may be necessary. Denials at the prior approval stage may occur for reasons **unrelated** to medical necessity (that do not require utilization review) such as, but not limited to, un-relatedness or non-compensability of the claim.

Prior Approval and Utilization Review

Q: What is the difference between prior approval (PA) and utilization review (UR)?

A: PA is defined in the section above. UR is used to determine "**medical necessity**"- the evaluation of necessity, appropriateness, efficiency and quality of the requested medication. (Rule 0800-02-17-.03(82)). If you receive a denial letter in the mail, take it to your physician for further consideration. This process may take more time and sometimes requires review by a peer physician. Be aware that denials at the prior approval stage may occur for reasons **unrelated** to medical necessity (that do not require utilization review) such as, but not limited to, un-relatedness or non-compensability of the claim.

Medications Covered by the Drug Formulary

Q: What drugs are subject to prior approval requirements?

A: The drug formulary utilizes the Work Loss Data Institute, Official Disability Guidelines (ODG®) Drug Appendix A as a basis, but also includes other specific medications. Please see instructions within the formulary rules for further information. "N" drugs ("Needs Prior Approval") as well as compounds, topicals, and investigational or experimental drugs yet to be identified as a "Y" or "N" drugs require prior approval. Insurers may exclude "N" drugs from prior approval in circumstances where the insurer has previously reviewed and approved these medications. For further instructions, go to:

<http://www.tn.gov/workforce/article/wc-drug-formulary>.

Q: Not addressed drugs – what happens to these?

A: Only those **classes** of drugs that contain medications that are listed as “N” are posted with the formulary. Those classes may contain “Y” drugs as well. Any classes of drugs that are not listed or are not specifically called out in the regulations should be treated similar to “Y” drugs.

Q: Are “Y” drugs subject to prior approval?

A: No. Only “N” drugs, compounds, topicals and investigational/experimental drugs require prior approval.

Q: Are refills of “N” drugs prescribed **or** dispensed (regardless of the DOI) prior to the initial formulary application date (August 28, 2016) allowed after the application date?

A: Yes, it is recommended but not required that an “N” drug that was prescribed **or** dispensed prior to August 28, 2016 that has remaining refills be treated as a “Y” drug for remainder of prescribed refills.

Q: Do current TN regulations addressing repackaged medications still apply?

A: Yes. These are addressed in the Medical Fee Schedule rules.

Q: Does the drug formulary rule supersede existing rules related to utilization review (UR) for Schedule II, III and IV drugs which are utilized for pain for periods greater than 90 days?

A: No. The drug formulary rules do not change or supersede the existing statute on these review procedures. UR may occur on Schedule II, III and IV drugs prescribed for pain management longer than 90 days from the initial prescription.

Q: Will current clinical edits and clinical tools be permitted on “Y” drugs after August 28, 2016?

A: The regulations state, “*Prescriptions for ‘Y’ drugs should be filled without delay if they are **approved as appropriate** for the nature of the injury being treated.*” Therefore, application of clinical edits and tools that may assist in determining this requirement are permitted. It is encouraged that the PBM and insurer share clinical information and treat each claim individually but also determine and quickly approve appropriate medications.

Q: Are there price caps associated with any of the meds or is there an overall price cap for TN?

A: No. Not in these rules. There are maximums established by the Medical Fee Schedule.

Q: Since “Y” drugs should be filled ‘without delay’ if they are approved and appropriate for the nature of the injury being treated, is UR allowed on “Y” drugs?

A: Yes. UR is permitted on “Y” drugs when required to determine appropriateness for the condition that is covered (medical necessity). This provision, however, should not be used prospectively or if the prescription may be covered under the “first fill” provisions listed below. It is the intent of the Bureau to avoid undue delays in the provision of “Y” drugs. UR review on “Y” drugs may be done retrospectively only in restricted circumstances.

Q: What are the restricted circumstances when retrospective UR may deny either a “Y” or “N” drug?

A: Retrospective UR is allowed **only** for drugs that are not medically necessary for the covered condition. This will only impact the next fill or refill and not the fill (medication) which has already been dispensed. If the medication is found to not be medically necessary

after UR, then the patient, physician, and pharmacist should be notified that the **next prescription (fill or refill)** will not be paid under workers' compensation, using the same procedures that are presently in effect. UR may still occur at 90 days for Schedule II, III, IV drugs used for pain management. (T.C.A. §50-6-102(20)).

Q: Can an adjuster deny a medication – including an “N” drug – based upon the medical necessity of the prescribed treatment?

A: Adjusters may not make denial decisions related to medical necessity. Under existing rules, denials based upon a question of medical necessity must go through **UR**. An adjuster may approve a medication (which may be “N” drug) but cannot deny based on medical necessity. This denial may *only* be made by a physician. Adjusters are encouraged to be aware of those claims that might be affected by the formulary and review them pro-actively to prevent any undue delays in approvals. Sharing this information between the PBM and the insurer is vital and an important link in providing appropriate and necessary medications in a timely manner.

First Fill Medications – Seven Days from Date of Injury (DOI)

Q: According to rules the injured worker is permitted seven days' worth of a medication for a first fill if that prescription is presented to the pharmacy within seven days from the date of injury. Is that correct?

A: Yes, that is correct. The seven-day supply of the medication (“N” or “Y” drug) is not reduced based upon the date of injury (DOI). An injured worker is entitled to a full seven days (of the date presented to the pharmacy) of a first fill medication as long as the prescription is presented to the pharmacy within seven days from the DOI or the date of surgery.

Q: Does this include “Y” and “N” drugs?

A: Yes. The rule states, *“Prescriptions presented to a pharmacy from an authorized provider and appropriate for the prescribed injury . . . even if the prescribed medication is status ‘N.’ The employer is responsible for the payment.”* Medications dispensed as part of a first fill during the first seven 7 days from the DOI (or date of surgery) are not subject to the formulary requirements and are required to be reimbursed as long as they are “appropriate” for the injury.

Request for Expedited Determination

Q: What if stopping my medication may cause medical problems?

A: The process of a **Request for Expedited Determination** can be initiated by the pharmacist or the physician on a form posted on the Bureau's web site under the Drug Formulary section. This process should only be used if there is anticipated to be a significant medical reason documented by the physician. All others should proceed through the regular procedures of appeal.