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New York Publishes Formal Draft Drug Formulary Rule

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The New York Workers' Compensation Board published a formal draft rule to establish a drug formulary. The proposed rule is the culmination of a multi-year effort involving two previously proposed drafts and public comment periods. The Board carefully examined comments from stakeholders on the previous drafts and posted their assessment of those comments with this rule.

This latest draft is a significant improvement over the previous proposals and more closely aligns with the best practices of drug formularies that a handful of other states have adopted. We appreciate the time and energy the Board has devoted to the development of this latest version.

The following is a summary of some of the main provisions of the rule:

The formulary contains a list of drugs that fall into three general categories: Phase A, Phase B and Perioperative.

Phase A

- Phase A drugs may be prescribed and dispensed without prior authorization and medical treatment guideline corroboration for up to a 30-day supply when prescribed within 30 days of the date of injury, until the carrier accepts the claim or the Board establishes the claim, whichever is earlier, except:
 - Phase A controlled substances and muscle relaxants indicated as a “1” in the “Special Considerations” column are limited to a single seven-day supply.
 - Phase A antibiotics and post-exposure medications indicated as a “2” in the “Special Considerations” column may be prescribed and dispensed for their prescribed full course of treatment.

- Phase A drugs not prescribed within the drug formulary guidelines require prior authorization.

Phase B

- Phase B drugs may be prescribed and dispensed without prior authorization for up to a 90-day supply after 30 days following the date of injury, when the carrier has accepted the claim or the Board has established the claim, whichever is earliest.
- Phase B drugs must be prescribed in accordance with the treatment guidelines.
- Phase B drugs indicated as “2nd” drugs may be prescribed and dispensed without prior authorization following trial of a first line Phase B drug.
 - Phase B antibiotics and post-exposure medications indicated as a “2” in the “Special Considerations” column may be prescribed and dispensed for their prescribed full course of treatment.
- Phase B drugs not prescribed within the drug formulary guidelines require prior authorization.

Perioperative

- Perioperative drugs may be prescribed and dispensed without prior authorization during the four days preceding and four days following surgery.
 - Perioperative controlled substance and muscle relaxants indicated as a “1” in the “Special Considerations” column are limited to a single seven-day supply.
 - Perioperative antibiotics and post-exposure medications indicated as a “2” in the “Special Considerations” column may be prescribed and dispensed for their prescribed full course of treatment.

Prior Authorization

- Prior Authorization is required for:
 - Phase A, Phase B or Perioperative drugs prescribed outside the formulary guidelines;
 - Brand drugs when a generic is available;
 - Non-formulary drugs;
 - Compound drugs with any non-formulary ingredient or if prescribed for other than an FDA-approved route of administration;
 - Formulary drugs prescribed in a manner not consistent with the medical treatment guidelines when a case has been accepted by the carrier or established by the Board.
- The rule introduces a new prior authorization process for prescription drugs.
 - When required, prior authorization must be sought before the drug is prescribed.
 - The prior authorization request may include the length of time the authorization is requested, not to exceed 365 days or the quantity of refills.
 - Prior authorization requests shall be approved, denied or partially approved within four calendar days.
 - Lack of response within the four days could lead to an approval order by the Chair.
 - There are two levels of review by the carrier:
 - First-level review is the initial review of the prior authorization request.
 - Second-level review can be requested by the prescriber within 10 days of a denial or partial approval following the first-level review and any denial or partial approval must be completed by the carrier's physician.
 - Denials on second-level review may be appealed for a third-level review by the Board.

- Prior authorization communication shall be made in an electronic format designated by the Board.

Other

- The formulary shall be updated not less than annually.
- If a conflict exists between the medical treatment guidelines and the drug formulary, the treatment guidelines prevail.
- The formulary applies to controverted claims.
- EFFECTIVE DATE-NEW PRESCRIPTIONS: The formulary will be effective six months from the effective date of the rule for all new prescriptions.
- EFFECTIVE DATE-REFILL AND RENEWAL PRESCRIPTIONS: The formulary will be effective twelve months from the effective date of the rule for all refill and renewal prescriptions (clarity is needed on this provision to ensure it only applies to refills and renewals prescribed prior to the effective date of the rule).

The Board will accept public comments on this proposed rule until February 22, 2019. Comments can be submitted via email to regulations@wcb.ny.gov.

A complete copy of the proposed rule text can be found [here](#).

The actual drug formulary list can be found [here](#).

The Board's assessment of previous public comment can be found [here](#).

We encourage stakeholders to review the rule and offer their comments to the Board.

For any questions concerning this alert or other regulatory or legislative action around the country, please contact Brian Allen, Vice President of Government Affairs, at Brian.Allen@mitchell.com or at 801.903.5754.



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