

Subchapter M of Chapter V of Title 12 of NYCRR is amended to add a new Part 441 as follows:

441 Formulary

441.1 Definitions.

- (a) “Compound drug” means a drug that is created by combining one or more active pharmaceutical ingredients, and/or one or more inactive ingredients, to meet specific patient medical needs that are not met with U.S. Food and Drug Administration (“FDA”)-approved prescription drugs, FDA-approved non-prescription drugs, or other drugs commercially available in the marketplace. For the purposes of this Part, a compound drug shall, at all times, be subject to federal law governing compounding, including title 21, United State Code, sections 353a, 353a-1 and 353b. A compound drug that incorporates a drug identified in Phase A or B of the Formulary or FDA-approved non-prescription drug may only be dispensed for the route of administration (oral, topical or systemic) for which it is FDA-approved. Prior authorization is required when a compound includes as an ingredient a prescription or non-prescription drug that is not identified in Phase A or B of the Formulary or is being prescribed for administration by means other than an FDA approved route of administration.
- (b) “Accident or injury” means any accident occurring in the course of employment or any alleged accident that results in personal injury which has caused or will cause a loss of time from regular duties of one day beyond the working day or shift on which the accident or alleged accident occurred, or which has required or will require medical treatment beyond ordinary first aid or more than two treatments by a person rendering first aid; or any disease or alleged disease claimed to have been caused by the nature of the employment and contracted therein. An accident or injury may also be referred to as a Disability event.
- (c) “Dispense,” “dispensed,” or “dispensing” means (1) the furnishing of a drug upon a medical prescription, or (2) the furnishing of drugs directly to a patient by a medical provider acting within the scope of his or her practice and pursuant to the dispensing limitations set forth in section 6807(2) of the Education Law.
- (d) “FDA-approved drug” means a prescription or nonprescription drug that has been approved by the FDA under the federal Food, Drug, and Cosmetic Act, title 21, United States Code, section 301 et seq. for the route of administration (oral, topical or systemic) prescribed.
- (e) “FDA OTC Monograph” means the data standards manual (DSM) established by the FDA setting forth acceptable ingredients, doses, formulations, and labeling for a class of over the counter drugs.
- (f) “Generic drug” means an FDA-approved drug that is therapeutically equivalent to a brand name drug, as determined by the FDA’s designation of the drug with the Therapeutic Equivalence Evaluation Code designation as an “A” product in the “Approved Drug Products with Therapeutic Equivalence Evaluations” (commonly referred to as the Orange Book), irrespective of dosage for the route of administration (oral, topical or systemic) prescribed. A brand name drug may not be dispensed when a generic version of the same active ingredient[s] is commercially available in a different strength/dosage. For example, if a drug is available generically in 5mg and 10mg tablets

and brand name only in 7.5mg tablets, the 7.5mg would be considered non-formulary and may not be dispensed without prior authorization.

- (g) “Carrier’s Physician” means a physician or physicians, licensed by New York State, or the appropriate state where the professional practices, who is:
 - 1. employed or contracted by the insurance carrier or self-insured employer; or
 - 2. is employed by a URAC accredited company retained by the insurance carrier or self-insured employer through a contract to review claims requests for non-formulary agents and advise the insurance carrier or self-insured employer; and
 - 3. is not employed or contracted by the carrier or self-insured employer’s pharmacy benefits network.
- (h) “Formulary” means the New York Workers’ Compensation Formulary which is a list of prescription and over-the-counter drugs for work-related injuries that is incorporated by reference in section 441.2 of this Part and that must be used to prescribe medication for all accidents or injuries. The Formulary includes medications available in Phase A and B; and, also includes a list of medications available for Perioperative periods that may be prescribed without Prior Authorization during the applicable Phase or Perioperative period.
- (i) “Non-Formulary drug” means a drug that does not appear on the Formulary and which is one of the following: an FDA-approved prescription drug; an FDA-approved nonprescription drug; or a nonprescription over the counter drug that is marketed pursuant to an FDA OTC Monograph. Non-Formulary drugs do not include non-FDA approved drugs and such drugs may not be prescribed. Medical marijuana prescribed and dispensed in accordance with Title V-A of the Public Health Law is not subject to this Part. The use of medical marijuana for work-related injuries will be regulated by the Board pursuant to section 324.3 of this Chapter, regardless of where the medical marijuana was prescribed or dispensed.
- (j) “Over-the-counter drug” means a drug that is available without a prescription. The carrier or pharmacy benefits manager should be billed for over-the-counter drugs included in the Formulary. Over-the-counter drugs that are not included on the Formulary require Prior Authorization or direct payment by the claimant (which thereafter may be submitted to the carrier in a reimbursement request [“M & T”]).
- (k) “Perioperative Formulary drug” are those drugs listed in the Perioperative Drug Formulary where the drug is prescribed for work-related injuries in accordance with subdivision (c) of section 441.4 herein.
- (l) “Phase A drug” are those drugs listed in Phase A of the Formulary. Phase A drugs may be prescribed and dispensed without Prior Authorization and Medical Treatment Guidelines corroboration when prescribed in accordance with subdivision (a) of section 441.4 herein.
- (m) “Phase B drug” are those drugs listed in Phase B of the Formulary and may be prescribed and dispensed without Prior Authorization and Medical Treatment Guidelines corroboration when prescribed in accordance with subdivision (b) of section 441.4 herein.
- (n) “Prior Authorization process” means the pre-approval review procedure initiated by the medical provider that is conducted prior to the prescribing or dispensing of a Non-Formulary drug; a brand-name drug when a Generic drug is available; or a Formulary

drug prescribed not in accordance with the applicable Phase of the Formulary or in accordance with applicable Medical Treatment Guidelines.

- (o) "Prior Authorization" means the carrier's approval of a Prior Authorization request initiated by the medical provider.
- (p) "Refill" means a fill of a prescription that is authorized at the point in time when the provider writes the original prescription and the number of such fills is explicitly included in the original prescription.
- (q) "Renewal" means a prescription that the claimant has been taking but for which there are no available refills and must be reinitiated by the provider writing a new prescription.
- (r) "URAC" means the Washington DC-based non-profit organization of that name that helps promote health care quality through the accreditation of organizations involved in medical care services.

441.2 New York Workers' Compensation Formulary

The New York Workers' Compensation Formulary, 1st edition (January 23, 2019), incorporated by reference herein, identifies drugs using three lists: a) Phase A for prescriptions within the first thirty days following a Accident or injury; b) Phase B for prescriptions after, the sooner of, the first thirty days following a Accident or injury or acceptance or establishment of the claim; and c) Perioperative for use during the Perioperative period. Copies of the Formulary may be downloaded from the Board's website free of charge. The Formulary may be examined at the office of the Department of State, 99 Washington Avenue, Albany, New York 12231, the Legislative Library, the libraries of the New York State Supreme Court, and the district offices of the Board, or obtained from the Board by submitting a request in writing, with a fee of five dollars, to the New York State Workers' Compensation Board, 328 State Street, Schenectady, New York 12305-2318. Payment of the fee shall be made by check or money order payable to "Chair WCB." Information about the Formulary can be requested by email at GENERAL_INFORMATION@wcb.ny.gov, or by telephone at 1-800-781-2362.

441.3 Applicability, Effective Dates and Notice.

The Formulary shall apply to all prescriptions following an accident or injury regardless of the date of accident or disablement and regardless of where the claimant lives. The Formulary shall be subject to the following:

- (a) Effective Dates
 1. New Prescriptions. Six months from the effective date of this Part, every new prescription shall be prescribed and dispensed consistent with the Formulary and this Part regardless of the date of accident or disablement and subject to any required Prior Authorization.
 2. Refill and Renewal Prescriptions. 12 months from the effective date of this Part, every refill and renewal prescription shall be prescribed and dispensed consistent

with the Formulary and this Part regardless of the date of accident or disablement and subject to any required Prior Authorization.

- (b) The Formulary shall apply to prescriptions for accidents or injuries that are controverted by the insurance carrier or self-insured employer.
- (c) The Pharmacy Fee Schedule set forth in Part 440 of this Subchapter remains in effect and includes pricing for prescriptions including Compound Drugs, the rules governing use of pharmacy networks and payments for prescriptions when the claim is controverted.
- (d) The Formulary shall not apply to drugs when such drugs are administered in a hospital or medical provider's office.
- (e) The Formulary shall apply to drugs that are dispensed by a medical provider acting within the scope of his or her practice and pursuant to the dispensing limitations set forth in section 6807(2) of the Education Law.
- (f) Notice. Within six months of the effective date of this Part, the insurance carrier or self-insured employer shall identify all claimants with current prescriptions for Non-Formulary drugs and provide written notification to the claimant and to the prescribing medical provider. Notice to the prescribing medical provider shall contain patient name, date of birth, date of accident, workers' compensation number and carrier case number as well as the following information: (1) the effective date and applicability of the Formulary and (2) a process for determining an equivalent Formulary drug (or a Generic drug subject to subparagraph [5] of subdivision [a] of section 441.5 herein); and (3) the process to request Prior Authorization for a non-Formulary drug. Notice to the claimant shall be in the format prescribed by the Chair.

441.4 Application of Formulary.

The Formulary identifies drugs using the generic or chemical name. The Formulary organizes these drugs into three lists identified below and includes both prescription and over-the-counter drugs. Over-the-counter Formulary drugs should be billed directly to the carrier or its pharmacy benefits manager.

- (a) Phase A: The drugs on this list may be prescribed and dispensed without obtaining Prior Authorization during the thirty days following an accident or injury or until the carrier accepts the claim or the Board establishes the claim, whichever is less, for up to a thirty days supply, subject to the following:
 - 1. Controlled substances and muscle relaxants may not exceed a single seven-day supply of a Formulary drug. These medications are indicated on Phase A of the Formulary as "1" in the "Special Considerations" column.
 - 2. Anti-infectives, including antibiotics and post-exposure medications, may be prescribed and dispensed in accordance with the prescribed course of treatment. These medications are indicated on Phase A of the Formulary as "2" in the "Special Considerations" column.
- (b) Prior Authorization is required for any Phase A drug that is not prescribed in accordance with this subdivision.
- (c) Phase B: The drugs on this list may be prescribed and dispensed, up to a 90- day supply, without obtaining Prior Authorization after 30 days following an accident or injury or

when the carrier has accepted the claim or the Board has established the claim. When a body part or illness has been accepted (with or without liability) or established, drugs must also be prescribed in accordance with, as applicable, the adopted Medical Treatment Guidelines. Phase B drugs designated as “2nd” Drugs may be prescribed and dispensed without Prior Authorization, following a trial of a first line drug prescribed in accordance with Phase B and, as applicable, the adopted Medical Treatment Guidelines.

1. Anti-infectives, including antibiotics and post-exposure medications, may be prescribed and dispensed in accordance with the prescribed course of treatment. These medications are indicated on Phase B of the Formulary as “2” in the “Special Considerations” column.
2. Prior Authorization is required for any Phase B drug that is not prescribed in accordance with this subdivision.

(d) Perioperative Formulary Drugs. Drugs listed as Perioperative Formulary drugs may be prescribed without Prior Authorization when prescribed during the perioperative period. The Perioperative period refers to the four days before and four days after the patient goes into the hospital, clinic, or doctor's office for surgery; with the day of surgery being day zero. Perioperative Formulary drugs may not be prescribed or dispensed outside of such perioperative period without Prior Authorization unless such drug is identified for the applicable Phase. Carriers should advise their pharmacy networks, including pharmacy benefit managers, when surgery has been authorized or scheduled.

1. Controlled substances and muscle relaxants may not exceed a single seven-day supply of a Formulary drug. These medications are indicated on the Perioperative Formulary as “1” in the “Special Considerations” column.
2. Anti-infectives, including antibiotics and post-exposure medications, may be prescribed and dispensed in accordance with the prescribed course of treatment. These medications are indicated on the Perioperative Formulary as “2” in the “Special Considerations” column.

441.5 Prior Authorization Process

(a) A medical provider must obtain Prior Authorization before prescribing or dispensing:

1. Phase A formulary drugs (including compound drug ingredients) other than as set forth in subdivision (a) of section 441.4 herein;
2. Phase B formulary drugs (including compound drug ingredients) other than as set forth in subdivision (b) of section 441.4 herein; or
3. Perioperative formulary drugs (including compound drug ingredients) other than as set forth in subdivision (c) of section 441.4 herein.
4. Brand name drugs for a generically available formulary drug, including a brand name drug available in a different dosage or strength.
5. Non-Formulary drugs;
6. Compound drugs with any Non-Formulary drug ingredient and/or for Formulary drugs being prescribed for other than an FDA approved route of administration.
7. Formulary drugs prescribed in a manner not consistent with the adopted Medical Treatment Guidelines when a case has been accepted by the carrier or established by the Board.

- (b) Prior Authorization must be sought and obtained prior to the time that the drug is prescribed and dispensed. The carrier or self-insured employer may deny payment when Prior Authorization was not obtained prior to dispensing the drug.
1. Prior Authorization must be sought and obtained for drugs listed in subdivision (a) of this section. Prior Authorization must be obtained:
 - i. when such drugs have been previously prescribed and dispensed prior to the effective date of the Formulary, or
 - ii. following completion or expiration of a previously approved Prior Authorization.
 2. When responsibility for payment is apportioned between more than one carrier or self-insured employer, the medical provider must seek Prior Authorization from all carriers and self-insured employers identified as having responsibility for payments for the work-related accident or injury. Any carrier or self-insured employer may approve or partially approve such Prior Authorization request and a subsequent denial or partial approval by any carrier or self-insurance carrier shall not affect the validity of the Prior Authorization approval.
- (c) Insurance carriers and self-insured employers shall provide the Chair or his or her designee in the manner prescribed by the Chair with the name and contact information for the point(s) of contact for the First level and Second level review within 30 days of the effective date of this paragraph. Such contact information may include the contacts' direct telephone number(s) and email address(es).
1. If the designated point(s) of contact changes at any time for any reason, the insurance carrier or self-insured employer shall notify the Chair or his or her designee of such change in the manner prescribed by the Chair.
 2. The list of designated points of contact for each insurance carrier and self-insured employer shall be posted on the Board's website. Any change in the designated contact shall not be effective until the designated contact information has been updated on the Board's website.
 3. In the event that a carrier or self-insured employer fails to provide the Chair or his or her designee with such name and contact information (in the manner prescribed) within 6 months of the effective date of this Subpart, or provides incorrect or incomplete contact information during initial registration or when updating pursuant to subparagraph (1) of this subdivision, such carrier may be subject to:
 - i. Orders of the Chair approving Prior Authorizations submitted during such time when the name and contact information is missing, incomplete or incorrect; and
 - ii. Penalties issued pursuant to section 114-a (3) of the Workers' Compensation Law for every case, where Prior Authorization was requested.
- (d) Insurance carriers and self-insured employers shall provide two levels of review as the Prior Authorization process. When a request for Prior authorization is approved or partially approved, the carrier may not thereafter deny payment for the approved

medication as set forth in section 440.5 of this chapter. The Prior Authorization process replaces the process set forth in section 324.3 of this Chapter (the variance process) for Non-Formulary drugs.

1. First level review. To initiate the Prior Authorization process, the medical provider shall submit a request for Prior Authorization to the insurance carrier, self-insured employer, or when designated by section 440.3 of this Subchapter, the pharmacy network, to the designated contact for First level review as described in subdivision (c) herein. Such request shall be submitted in the manner prescribed by the Chair.
 2. A Prior Authorization request for a Non-Formulary drug may include the requested length of time that the Prior Authorization will remain in effect or the quantity prescribed and the number of refills. In no event may a Prior Authorization request exceed 365 days. If the requested length of time for the Prior Authorization is not stated, the default shall be 30 days.
 3. The carrier, self-insured employer, or pharmacy benefits manager shall approve, partially approve or deny a Prior Authorization request within four calendar days of submission by a provider.
 - i. A partial approval authorizes the requested drug but limits the length of time, quantity prescribed or number of refills from that requested by the medical provider.
 - ii. A request for Prior Authorization that is not responded to within four calendar days (by an approval, denial or partial approval) may be approved for the period requested upon issuance of an Order of the Chair. A carrier may not object to payment in accordance with section 440.5 of this Subchapter for Non-Formulary drugs approved by an Order of the Chair and any such objection or non-payment may be subject to penalties pursuant to section 114-a(3) of the Workers' Compensation Law.
 4. A partial approval or denial of a request for Prior Authorization must:
 - i. Provide a specific reason for the denial or partial approval with reference to the specific Prior Authorization request made by the medical provider.
 - ii. Provide information regarding how to request review of the denial from the Carrier's Physician.
- (e) Second level review by carrier or self-insured employer's physician(s) (Carrier's Physician). Within 10 calendar days of a denial or partial approval of a Prior Authorization request, the medical provider may request review of such denial or partial approval by the Carrier's Physician.
1. Such request shall be made to the designated contact for Second level review as described in subparagraph (c) herein and shall include information that is responsive to the denial or partial approval at the first level.
 2. The carrier shall approve, partially approve or deny a Prior Authorization request within four calendar days.
 3. Only a Carrier's physician may issue a denial or partial approval of a Prior Authorization request.

4. A request for Prior Authorization that is not responded to within four calendar days (by an approval, denial or partial approval) may be approved for the period requested upon issuance of an Order of the Chair. A carrier may not object to payment in accordance with section 440.5 of this Subchapter for Non-Formulary drugs approved by an Order of the Chair and any such objection or non-payment may be subject to section 114-a(3) of the Workers' Compensation Law.

441.6 Review by the Board of a Prior Authorization Denial.

- (a) If the Carrier's Physician issues a denial or a partial approval, the medical provider may seek review by the Board's Medical Director's Office. The medical provider may not seek review by the Board's Medical Director's Office unless the medical provider has received a denial or partial approval by the Carrier's Physician.
- (b) All requests for review of denials or partial approvals of a Prior Authorization request shall be submitted to the Medical Director's Office in the format prescribed by the Chair. The Chair or Medical Director may designate private entities to evaluate such requests for review of denials by a Carrier's Physician provided that the entity has:
 1. the appropriate URAC accreditation or such accreditation/certification as designated by the Chair,
 2. other demonstrated expertise and criteria established by the Board; and
 3. no conflict of interest exists in resolving the subject dispute.
- (c) When a prescribing medical provider wishes to request review of a denial or partial approval of a Prior Authorization request, the medical provider shall submit the request to the Medical Director's Office in the format prescribed by the Chair within 10 calendar days of the denial date together with all documentation submitted in support of its First and Second level carrier review, and the denial or partial approval issued following such First and Second level reviews.
- (d) A decision by the Medical Director's Office (or designated accredited entity) is final and binding on the medical provider, the carrier, self-insured employer or pharmacy network. Such decision shall be binding and not appealable under Workers' Compensation Law section 23.
- (e) Notwithstanding paragraph (d) herein, a claimant may request review of a Medical Director's Office decision, by filing a Request for Further Action, that demonstrates that such drug is medical necessary and denial or Prior Authorization adversely impacts the claimant's interests. The Board may respond to such requests for review by letter or by referral to adjudication, as appropriate in the discretion of the Chair or his or her designee. Such decisions shall be binding and not appealable under Workers' Compensation Law section 23.
- (f) In the event that a Prior Authorization request is denied on the merits, the medical provider may not submit a request for Prior Authorization for the same prescription unless he or she submits evidence that there has been a change in the claimant's medical condition that renders the denial of the request for Prior Authorization no longer applicable to the claimant's current medical condition.

- (g) All communications regarding Prior Authorization shall be by the means of electronic delivery the Chair has designated for this purpose, unless the prescribing medical provider has sent a certification to the Board's Medical Director's Office that it is not equipped to send or receive Prior Authorization requests by electronic means. Such certifications must include an attestation that the prescribing medical provider is unable to send or receive Prior Authorization requests by electronic means.

441.7 Changes to the Formulary.

(a) The Formulary shall be updated, not less than annually, to account for changes to medications available on the market.

(b) The Medical Director and/or Chair, or his or her designees, shall review any drugs recommended for addition or removal from the Formulary, and assess requests regarding drugs included and/or excluded from the Formulary. Written documentation of the review and assessment of changes to the Formulary shall be maintained by the Board and posted on the Board's website. Decisions regarding changes to the Formulary shall be binding and not appealable under Workers' Compensation Law section 23.

441.8 Medical Treatment Guidelines and Formulary.

In the event that a conflict exists between the Board's medical treatment guidelines and the New York Formulary, the provisions of the medical treatment guidelines shall prevail, unless the drug was prescribed in accordance with Phase A or Phase B of the Formulary.