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Understanding Variances and The Drug Formulary

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Understanding Variances

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Medical Treatment Guidelines

The Medical Treatment Guidelines (MTG) adopted by the NYS Workers' Compensation Board (WCB) are the mandatory standard of care for injured workers incorporated into Workers' Compensation Regulations (12 NYCRR, Part 324).

- Medical providers are required to treat all workers with existing or new workers' compensation injuries, consistent with the MTG recommendations.
- The MTG apply to care provided within or outside of New York State.

Medical Treatment Guidelines

All medical care described in the MTG and performed consistent with the recommendations in the MTG is authorized and the health care provider is not required to obtain prior authorization with *limited exceptions that are clearly defined in the MTG*.

- There are currently six MTG - Low Back (LB), Neck, Shoulder, Knee, Carpal Tunnel Syndrome (CTS) and None-Acute Pain (NAP0. Additional Guidelines are in development.

MTG Limited Exceptions

That require pre-authorization include:

1. Lumbar fusion
2. Artificial disc replacement
3. Spinal cord stimulators
4. Electrical bone stimulation
5. Vertebroplasty
6. Kyphoplasty
7. Chondroplasty
8. Autologous chondrocyte implantation
9. Osteochondral autograft
10. Meniscal allograft transplantation
11. Knee arthroplasty (full or partial knee joint replacement)
12. "Repeat surgery"

Medical Treatment Guidelines

- Prior authorization is required for “repeat surgery” which is defined as any second or subsequent procedures (the repeat performance of a surgical procedure due to failure of, or incomplete success from the same procedure performed earlier, if the MTG do not specifically address multiple procedures).
- A **C-4 AUTH Form** must be used to request prior authorization for these exceptions.

Variations: 12 NYCRR Section 324.3

Regulations define:

- Who can request a variance?
- What is a variance?
- When is a variance permitted?
- What is required?
- How to request a variance?
- How to obtain review of a variance denial?

Who Can Request a Variance?

Treating Medical Provider (Provider)*

- Physician
- Chiropractor
- Psychologist
- Podiatrist

*Note: Additional providers will be recognized in the near future as a result of the Expanded Provider Legislation.

What Is A Variance?

- Variances allow for flexibility in care.
- When a Provider determines that medical care that varies from the MTG is **appropriate** and **medically necessary**, a variance should be requested.
- The burden of proof* to establish that a variance is appropriate and medically necessary rests with the Treating Medical Provider requesting the variance.

*Burden of Proof: Documentation that supports statement of medical necessity.

When Is A Variance Permitted?

Regulations identify three circumstances under which a variance may be requested:

- When extending duration of therapy beyond maximum duration recommended in the MTG.
- When treating outside the recommendations in the MTG.
- Where the condition, treatment or diagnostic test for a covered body part is not addressed in the MTG.

What Is Required For A Variance?

All variance requests must include a medical opinion by the provider that documents:

- The basis for the proposed care;
- Why it is medically necessary and appropriate to deviate from the MTG;
- Explanation of why MTG alternatives are not appropriate or sufficient; and
- Statement that the patient agrees to the proposed care.

What Is Required For A Variance?

Additionally, requests for treatment that is not recommended or not addressed in the MTG must include:

- A description of signs/symptoms that did not improve with care provided in accordance with MTG.
- Providers may submit citations or copies of relevant literature published in peer-reviewed medical journals in support of a variance request.

Medical Treatment Guidelines

As defined in the regulations (Section 324.1 (b)), **care must be provided “consistent with the MTG.”**

This is a two-pronged test:

1. Care must be provided within the criteria or in accordance with the recommendations of the MTG, and
2. Based upon a correct application of the MTG, which requires the integration of the General Guideline Principles with the specific MTG recommendations.

What Is Required For A Variance?

MTG General Principles

- Are necessary to appropriately apply and interpret MTG recommendations.
- Provides framework for documenting medical necessity.
- Provides guidance in identifying appropriate goals and outcomes of treatment.
- Are located in the first section of each MTG.

What Is Required For A Variance?

MTG General Principles

Medical Care section is comprised of four general principles:

- Medical Care (focus on functional ability).
- Rendering of Medical Services (standard of care).
- Positive Patient Response.
- Re-evaluate treatment.

What Is Required For A Variance?

Application of MTG General Principles

Principle 1:

- Medical Care and treatment required as a result of a work-related injury should be focused on restoring functional ability required to meet the patient's daily and work activities and return to work, while striving to restore the patient's health to its pre-injury status, as is feasible.

What Is Required For A Variance?

Application of MTG General Principles

Principle 2:

- Rendering of medical services is a restatement of the fact that the Medical Treatment Guidelines are the standard of care for injured workers.

What Is Required For A Variance?

Application of MTG General Principles

Principle 3:

- Positive Patient Response or positive results are **defined primarily as functional gains which can be objectively measured.**

What Is Required For A Variance?

Application of MTG General Principles

Principle 3: Positive Patient Results (cont'd)

- Objective functional gains include, but are not limited to:
 - Positional tolerances,
 - Range of motion,
 - Strength,
 - Endurance, and/or
 - Activities of daily living.

What Is Required For A Variance?

Application of MTG General Principles

Principle 4: Re-Evaluate Treatment

- Efficacy of the treatment or modality should be documented by the provider:
 - 2-3 weeks after the initial visit; and
 - 3-4 weeks thereafter.

What Is Required For A Variance?

Application of MTG General Principles

Principle 4: Re-Evaluate Treatment (con't)

- If a treatment is not producing positive results, the provider should:
 - Modify or discontinue the treatment regime, or
 - Reconsider the diagnosis in the event of a poor response to a rational intervention.

Documenting Objective Functional Improvement

Three basic components:

1. Initial evaluation

- What were the patient's functional abilities at the time of the initial or previous assessment? (post-injury)

2. Re-evaluation

- What are the patient's functional abilities now, at the time of the re-evaluation?

Documenting Objective Functional Improvement

3. Goals

- What goals do you expect the patient to reach at the next evaluation? What type of treatment is planned to reach these goals?
- Ultimate goals: Should be focused on return to work, work activities, and identified limitations. What are the work activities that the patient was able to perform prior to the injury and must be able to perform in order to return to work?

Variance Request for Ongoing PT

Example #1

- 46 year old man
- Low back injury
- Receiving ongoing PT
- Not working
- Medical Necessity: Continue PT modalities for LBP

Variance Request for Ongoing PT

PT progress notes essentially unchanged when comparing notes from visit to visit.

- PT three times per week.
- Goals: Decrease pain, increase ROM and strength.
- Treatment plan: Laundry list of modalities.

Variance Request for Ongoing PT

PT Treatment Plan:

- Lumbar rehabilitation, therapeutic massage, physical therapy, biofeedback, nerve block, laser therapy, trigger point therapy, spray and stretch, hot and cold packs, electrical muscle stimulation, ultrasound, passive and active range of motion, abdominal and paraspinal strengthening, stretching exercises to be continued.
- Three times per week for six weeks with re-evaluation thereafter.
- Patient tolerated treatment without adverse effect.

Variance Request for Ongoing PT

Example #2:

- 50 year old man
- Low back injury
- Receiving PT
- Working

Variance Request for Ongoing PT

Medical Necessity: Patient has returned to work in housekeeping. Needs more time to complete chores at work since he is not able to carry enough bulk linens and other supplies as required.

Goals: Therapeutic exercise to increase musculoskeletal strength lumbar spine to fulfill job functions with minimal to no pain.

Plan: PT/Therapeutic exercise 3x/week for 4 weeks to increase strength, endurance and ability to perform work activities.

Variance Request for Ongoing PT

Therapeutic exercise program:

- Exercise gym ball, pelvic tilt, bridging, bicycle ergometer, AROM using weights, prone hip extensions, prone on elbows, heat/cold.
- Progressive weights, reps and resistance towards goal of increased carrying and lifting (from floor) to perform work activities.
- Re-evaluate in four weeks .
- Transition to a home exercise/self management program.
- Training in appropriate techniques to avoid re-injury.

How To Request A Variance?

The provider must:

1. Fill out forms (MG-2) correctly and accurately with emphasis on medical documentation necessary to support the care requested.
2. Complete addendum (MG-2.1) to request a variance for more than one test/procedure.
3. Request a variance before care that varies from the MTG is performed.

How To Request A Variance?

The carrier has:

- 15 days to respond to variance request.
- 5 days to notify if an IME will be obtained and 30 days to respond to request if IME is performed (record review or exam).

Substantially Similar Requests

1. **“Substantially similar” requests are prohibited. Substantially similar requests are variance requests that are either submitted:**
 - a. Before the time for review has expired, or
 - b. If the original request was denied, without additional medical documentation to justify the request.
2. **Carrier may deny “substantially similar” requests from the same provider without a medical opinion from its medical professional, record review or IME.**

How To Obtain Review Of A Variance Denial?

If carrier denies the variance, claimant has 21 days to request a review of the denial.

- Claimant consults with Provider to determine if requested care is still necessary, and
- Completes appropriate section of MG-2 form to request review.

Two mechanisms of review:

- Expedited hearing, or
- Medical Arbitration by Medical Director's Office (MDO).

How To Obtain Review Of A Variance Denial?

A request for review of a variance denial is directed to medical arbitration (MDO) unless the injured worker or the insurer requests review by a workers' compensation law judge.

- The request for review by a medical arbitrator or a law judge may be made on a case-by-case basis.

How To Obtain Review Of A Variance Denial?

Resolution by Adjudication will proceed by Proposed Decision.

- If the Proposed Decision does not resolve the issue, it will proceed to hearing.
- Resolution by Arbitration is binding and not appealable under Workers' Compensation Law 23.

What if the Insurer/Carrier Does Not Respond to the MG-2

Insurer has 15 days to respond to a variance request

- If the insurer wishes to obtain an IME or review of records, notification of this determination must be made to the Provider and Chair within five days of receipt of the request.
- A response to the variance request must be submitted within 30 days of the receipt of the request.

What if the Insurer/Carrier Does Not Respond to the MG-2

- A valid variance may be deemed approved by an *Order of the Chair* if the insurer fails to respond to a properly completed request within required time frames.

Resources for Variances

Board's Website: <http://www.wcb.ny.gov/content/main/hcpp/hcpp.jsp>



Medical Director's Office contact information:

- 800-781-2362
- WCBMedicalDirectorsOffice@wcb.ny.gov



Workers' Compensation Board



The Drug Formulary

Drug Formulary Background

2017

- Legislation was signed in April 2017 that required New York State Workers' Compensation Board (Board) to establish a comprehensive prescription drug formulary by December 31, 2017.
- On December 28, 2017, the Board announced (Subject Number 046-1012) the creation and release of the proposed formulary and sought public comments.

Drug Formulary Background

2018 - 2019

- October 17, 2018, the Board revised the proposed NYS Workers' Compensation Drug Formulary (Formulary) in Subject Number 046-1112 in response to public comment.
- January 23, 2019, the Board released Subject Number 046-1133 announcing a revised version incorporating additional public comments.

The Drug Formulary

- Based on a medication's effectiveness and appropriateness for the treatment of illnesses and injuries covered under the Workers' Compensation Law (WCL).
- Consistent with the applicable Medical Treatment Guidelines (MTGs).

Note: The Formulary does not apply to drugs **administered** in a hospital or medical provider's office.

Formulary Implementation Timeline

5/21/19 – Adopted by Regulation

6/5/19 – Formulary Effective

12/5/19 – New prescriptions must comply

6/5/20 – Refill prescriptions must comply

Application of the Formulary

Formulary consists three drug lists:

- Phase A drugs
- Phase B drugs
- Perioperative drugs

The drugs on each list are prescribed according to the following framework.

Application of the Formulary

Phase A

Drugs on this list may be prescribed and dispensed:

1. Within the first 30 days following an accident or injury, or when the carrier accepts the claim or the Board establishes a claim, whichever occurs sooner.
2. For up to a 30-day supply, unless a Special Consideration is identified.

Application of the Formulary

Phase B

Drugs on this list may be prescribed and dispensed:

1. After 30 days following an accident or injury.
2. Or, less than 30 days after the date of injury if the carrier has accepted the claim or the Board has established a claim.
3. For up to a 90-day supply, unless a Special Consideration is identified.

Application of the Formulary

Phase B (cont'd)

4. When a body part or illness has been accepted (with or without liability) or established, drugs must be prescribed in accordance with, as applicable, the MTG.
5. Phase B drugs designated as “2nd” may be prescribed and dispensed following an unsuccessful trial of a first line drug prescribed in accordance with Phase B and, as applicable, the adopted MTG.

Application of the Formulary

Perioperative Drug List

- Drugs approved for use during the perioperative period (four days before through four following surgery).

Application of the Formulary

Second-Line Drugs

- Drugs designated as second line may be prescribed and dispensed following a trial of a first-line drug prescribed in accordance with Phase B and, as applicable, the adopted MTG.

Application of the Formulary

Special Considerations Include:

- “1” – Not to exceed a single (7) day supply
 - Meaning the Formulary drug can be prescribed and dispensed:
 - One time only, without a prior authorization.
 - For a maximum of a seven-day supply.
 - During the phase of the Formulary under which it is contained.
 - Example: narcotics during the perioperative period.

Application of the Formulary (con't)

Special Considerations (cont'd):

- “2” – For the prescribed course of therapy
 - Meaning the item can be prescribed or dispensed:
 - During the applicable phase of the Formulary.
 - For the course of treatment indicated by the prescriber.
 - Example: antibiotics.

Application of the Formulary (con't)

Special Considerations (cont'd):

- “3” – Short acting formulation only
 - Meaning the item can be prescribed or dispensed:
 - For the short acting formulation of the medication only
 - Example: opioids / skeletal muscle relaxant.

Formulary Format

Therapeutic Category	Generic Name	Special Considerations	Phase A	Phase B	Foot Operative	Ankle / Foot	Asthma	Back Mid / Low (MTG)	Carpal Tunnel (MTG)	CRPS	Elbow	Eye	Hip / Groin	Knee (MTG)	Neck (MTG)	Pain Non Acute (MTG)	Shoulder (MTG)
Antihistamines	Hydroxyzine		x	x													
Antihistamines	Levocetirizine		x	x													
Antihistamines	Loratadine		x	x													
Antihistamines	Promethazine		x	x													
Antihypertensive	Clonidine HCl		x														
Antihypertensive	Lisinopril		x														
Antihypertensive	Losartan		x														
Antihypertensive	Prazosin		x														
Anti-infectives, Misc.	Clindamycin	2	x	x		Yes					Yes		Yes				Yes
Anti-infectives, Misc.	Linezolid	2		x													
Anti-infectives, Misc.	Metronidazole	2	x	x		Yes					Yes		Yes				Yes
Anti-infectives, Misc.	Sulfamethoxazole-Trimethoprim	2	x	x		Yes					Yes		Yes				Yes
Anti-infectives, Misc.	Vancomycin	2	x	x													
Anti-inflammatory	Celecoxib			x		2nd		2nd	2nd	2nd	2nd		2nd	2nd	2nd	2nd	2nd
Anti-inflammatory	Diclofenac		x	x	x	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Anti-inflammatory	Etodolac		x	x	x	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Anti-inflammatory	Ibuprofen		x	x	x	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Anti-inflammatory	Indomethacin		x	x	x	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Anti-inflammatory	Meloxicam		x	x	x	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Anti-inflammatory	Naproxen		x	x	x	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Anti-inflammatory	Sulindac		x	x	x	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Antimalarial	Hydroxychloroquine		x	x	x	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Antineoplastic	Cabozantinib	2		x													
Antineoplastic	Dabrafenib			x													

Formulary: Over-The-Counter Drugs

- Certain OTCs are included in the Formulary.
- When a prescription is written, the OTC will be processed by the pharmacy and paid for by the carrier.

When Is Prior Authorization Required?

A medical provider must request and obtain Prior Authorization from the insurer or self-insured employer before prescribing or dispensing:

1. A drug not listed on the Formulary.
2. A brand name drug, when a Formulary generic is available.
3. Combination products, unless specifically listed on the Formulary.

When Is Prior Authorization Required?

4. A brand name drug when a generic version of the same active ingredient(s) is commercially available in a different strength/dosage:
 - Example: a product is generically available in 5mg and 10mg, and the brand in 7.5mg. The 7.5mg product would be considered non-Formulary and could only be dispensed subsequent to a prior authorization.
5. Any compounded drug.

Note: The carrier or self-insured employer may deny payment when Prior Authorization was *not* obtained.

Medical Providers' Role in Obtaining a Prior Authorization

- A health care provider is responsible for obtaining necessary prior authorization, using the WCB Medical Portal application, before prescribing or dispensing a non-Formulary medication.
- There may be up to three levels of review associated with a prior authorization.
 - Level I
 - Level II
 - Level III

Note: All requests will be made in the manner prescribed by the Chair.

Medical Providers' Role in Obtaining a Prior Authorization

Level I: Request

- The prior authorization review request is submitted to designated insurance carrier, self-insured employer, or pharmacy benefit manager (PBM):
 - a. Specific drug requested including quantity prescribed and number of refills included: up to a maximum of a 365-day supply.
 - b. Clinical information to support the request for the non-Formulary drug.

Note: If requested duration of therapy is not specified, the default will be 30 days.

Carrier's Response to Prior Authorization Request

Level I: Request

- The insurance carrier, self-insured employer, or pharmacy benefits manager must approve, partially approve or deny the request within four calendar days of the medical provider's submission of the request.

NOTE: A partial approval would be a limitation in duration or quantity approved. A prior authorization request maybe deemed 'approved' in the absence of a carrier response within four calendar days.

Carrier's Response to Prior Authorization Request

Level I: Response

- A partial approval or denial of a request for prior authorization must:
 - Specifically respond to the documentation submitted by the prescriber setting forth the reason(s) for the carrier's determination.

Medical Providers' Role in Obtaining a Prior Authorization

Level II: Request

- Provider may request a carrier's review of a Level I determination within 10 calendar days of receipt of the determination.
- Provider must submit additional clinical information to support the review request specifically addressing the issues cited in the carrier's Level I determination.

Carrier's Response to Prior Authorization Request

Level II: Response

- Performed by the carrier's physician(s).
- Within four calendar days of the receipt of the Level II review request.
- Specifically respond to the documentation submitted by the prescriber setting forth the reason(s) for the carrier's determination.

Medical Providers' Role in Obtaining a Prior Authorization

Level III: Request

- Provider may request a review of a Level II determination within 10 calendar days of receipt of the determination.
- Provider must submit additional clinical information to support the review request specifically addressing the issues raised in the carrier's Level II determination.

Response to a Level III Review Request

Level III: Review

- The Board's Medical Director's Office (MDO) will review all Level III review requests in a timely fashion.
- The decision by the MDO is binding and not appealable under WCL Section 23.

Resources for Drug Formulary

For more detailed information about the WCB Drug Formulary and the Prior Authorization process, please see:

www.wcb.ny.gov/drug-Formulary-regulation/Text-Part-441-drug-Formulary.pdf

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