

Disclaimer

This presentation is for educational purposes only and provides general information. It is not a substitute for full review of statutes and rules.

System participants are responsible for knowing and complying with the applicable sections of the Texas Insurance Code, Texas Labor Code, and Texas Administrative Code.

Any opinions expressed by the speakers are personal, and do not constitute or reflect any statement of policy by the Texas Department of Insurance, Division of Workers' Compensation.

Topics Covered

Texas Department of Insurance, Division of Workers' Compensation Overview

Pharmacy Formulary Rule History & Development

Pharmacy Closed Formulary Amended and New Rules

Case Scenarios and Resources

Texas Department of Insurance, Division of Workers' Compensation Overview

Texas Department of Insurance

The Texas Department of Insurance (TDI) envisions a financially stable and fair marketplace and an effective and efficient workers' compensation system.

The mission of TDI is to protect insurance consumers by regulating the insurance industry fairly and diligently with the Texas Insurance Code.

Texas Department of Insurance, Division of Workers' Compensation

The primary duties of the Division of Workers' Compensation (DWC) are to:

- Regulate and administer the business of workers' compensation in Texas; and
- Ensure that the Texas Workers' Compensation Act, Texas Labor Code, and other laws regarding workers' compensation are implemented and enforced.

Texas Department of Insurance

Division of Workers' Compensation (DWC)

- Non-network claims
- Political subdivisions

Managed Care Quality Assurance (MCQA) Office

- Certified Workers' Compensation Health Care Networks (WCNet) - network claims
- Political subdivisions that use a WCNet

Texas Workers' Compensation Regulation

TEXAS STATUTES

TEXAS INSURANCE CODE (TIC)

Titles 2, 8, and 14

TEXAS LABOR CODE

Title 5

TEXAS ADMINISTRATIVE CODE

TITLE 28

PART 1

Texas Department of Insurance

PART 2

Texas Department of Insurance,

Division of Workers' Compensation

Pharmaceutical Benefits

Texas Labor Code §408.021

An employee who sustains a compensable injury is entitled to all health care reasonably required by the nature of the injury as and when needed. The employee is specifically entitled to health care that:

- cures or relieves the effects naturally resulting from the compensable injury;
- promotes recovery; or
- enhances the ability of the employee to return to or retain employment.

Pharmaceutical Benefits

That means....

A physician providing care may prescribe any necessary prescription drugs, and order over-the-counter alternatives to prescription medications as clinically appropriate in accordance with state law and the Texas Workers' Compensation Act.

Pharmacy Formulary Rule History & Development

79th Texas Legislature passed HB-7, which amended Texas Labor Code §408.028. Pharmaceutical Services:

"...The commissioner by rule shall adopt a closed formulary under Section 413.011. Rules adopted by the commissioner shall allow an appeals process for claims in which a treating doctor determines and documents that a drug not included in the formulary is necessary to treat an injured employee's compensable injury."

DWC:

- Conducted stakeholder meetings
 - August 2008
 - March 2009
 - August 2009
- Posted 3 informal working drafts of the rules prior to formal proposal
 - 12/16/2008
 - 06/12/2009
 - 02/04/2010

Professional medical and pharmacy associations were involved in providing stakeholder input, some examples are:

- Texas Medical Association
- Texas Pain Society
- Texas Pharmacy Association
- Texas Osteopathic Medical Association
- Texas Orthopedic Association

July 16, 2010

Proposed closed formulary rules published in the *Texas Register*.

August 16, 2010

Public hearing and close of public comments.

December 17, 2010

Adopted closed formulary rules published in the December 17, 2010 *Texas Register* and with corrected effective date of *January 17, 2011* in the January 14, 2011 edition of *Texas Register*.

28 Texas Administrative Code Chapter 134 Benefits--Guidelines For Medical Services, Charges, And Payments Subchapter F: Pharmaceutical Benefits

Amended Rules

§134.500 – Definitions

Includes key definitions pertaining to all pharmaceutical benefits rules.

§134.506 - Outpatient Open Formulary for Claims with Dates of Injury Prior to September 1, 2011

 Addresses the formulary that applies to "legacy claims."

New Rules

§134.510 - Transition to the Use of the Closed Formulary for Claims with Dates of Injury Prior to September 1, 2011

- Addresses transition to the closed formulary for "legacy claims".
- §134.520 Outpatient Closed Formulary for Dates of Injury On or After September 1, 2011
 - Applies the closed formulary to dates of injury September 1, 2011 and forward.

New Rules

§134.530 - Requirements for Use of the Closed Formulary for Claims Not Subject to Certified Networks

 Describes the requirements for use of the closed formulary for non-network claims.

§134.540 - Requirements for Use of the Closed Formulary for Claims Subject to Certified Networks

 Describes the requirements for use of the closed formulary for certified network claims.

New Rule

§134.550 - Medical Interlocutory Order (MIO)

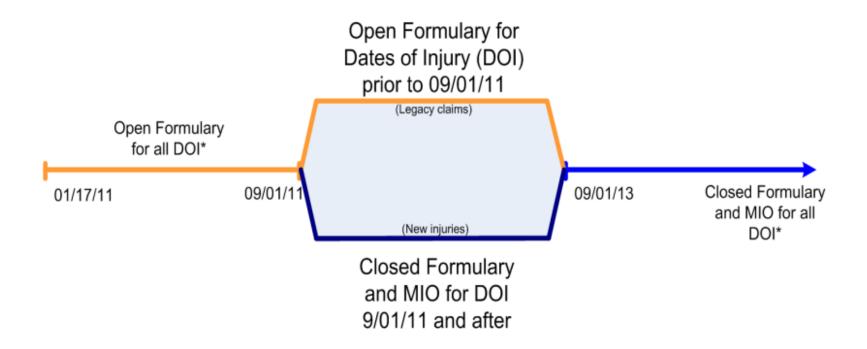
 Outlines a process for access to drugs excluded from the closed formulary that are denied preauthorization where unreasonable risk of a medical emergency exists.

Amended Rule

§133.306 – Interlocutory Order for Medical Benefits

 The commissioner may delegate authority to DWC staff to issue an interlocutory order for future or accrued medical benefits.

Timeline of the Closed Formulary Implementation



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*Except Old Law Claims (DOI Dec 31, 1990 and before)



§134.500 Definitions

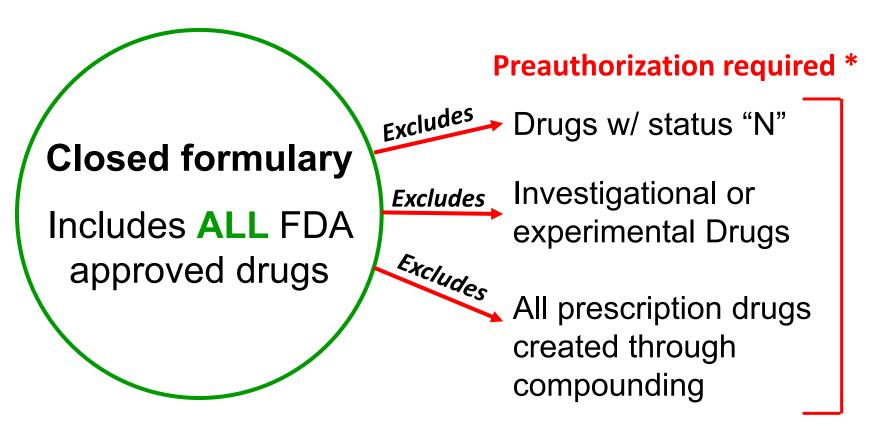
Closed Formulary

All available Food and Drug Administration (FDA) -approved prescription and non-prescription drugs prescribed and dispensed for outpatient use with some exclusions.

Exclusions from the closed formulary:

- drugs with "N" status identified in the current edition of the Official Disability Guideline (ODG) Treatment in Workers' Comp/ Appendix A, ODG Workers' Compensation Drug Formulary and any updates;
- any compound that contains a drug identified with an "N status; and
- any investigational or experimental drug as defined in Texas Labor Code §413.014(a).

Pharmacy Formulary and Preauthorization

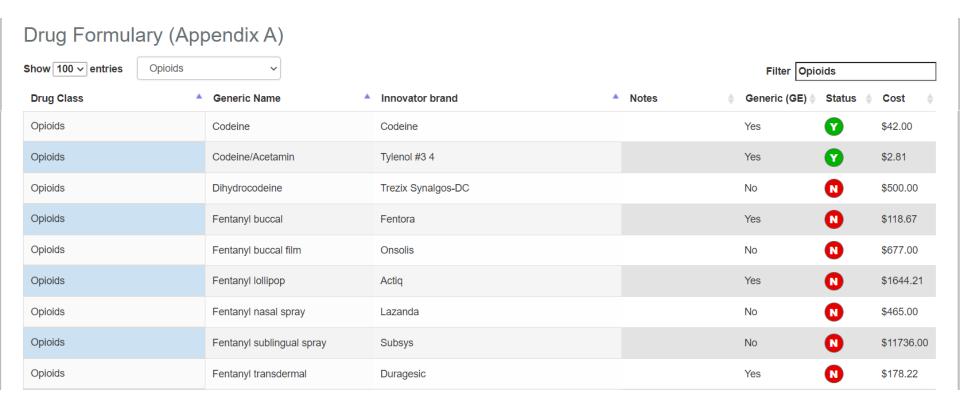


^{*}After initial pharmaceutical coverage 28 TAC §134.501 Initial Pharmaceutical Coverage

"N" Status Drugs

- ODG's appendix A is the most current publication for "N" status drugs.
 www.mcg.com/odg/
- DWC will post the "N" status drugs from ODG's Appendix A on its website.
 www.tdi.texas.gov//wc/pharmacy/index.html
- "N" status drugs is updated monthly.

ODG Appendix A



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Appendix A on the DWC website



Texas Department of Insurance

Division of Workers' Compensation

This table is provided as a convenience only and is not a substitute for the current edition of ODG Treatment in Workers' Comp / Appendix A:

ODG Workers' Compensation Drug Formulary (see memo).

Appendix A, ODG Workers' Compensation Drug Formulary (March 31, 2022)

ODG Workers' Compensation Drug Formulary

Drug Class	Generic Name	Brand Name	Gener Equiv	Status	Notes
Opioids	Codeine	Codeine	Yes	Υ	
Opioids	Codeine/Acetamin	Tylenol #3 4	Yes	Υ	
Opioids	Dihydrocodeine	Trezix Synalgos-DC	No	N	
Opioids	Fentanyl buccal	Fentora	Yes	N	
Opioids	Fentanyl buccal film	Onsolis	No	N	
Opioids	Fentanyl lollipop	Actiq	Yes	N	
Opioids	Fentanyl nasal spray	Lazanda	No	N	
Opioids	Fentanyl sublingual spray	Subsys	No	N	
Opioids	Fentanyl transdermal	Duragesic	Yes	N	
ReadMe 2019	April 2022 Revised April	2022 March 2022 February 202	2 January 20	22 De	cembe 🗭 :

Open formulary

Includes all available Food and Drug Administration (FDA) approved prescription and nonprescription drugs prescribed and dispensed for outpatient use, but does not include drugs that lack FDA approval, or nondrug items.

Statement of medical necessity

A written statement from the prescribing doctor to establish the need for treatments or services, or prescriptions, including the need for a brand name drug where applicable.

Statement of medical necessity must include:

- the injured employee's full name, DOI, SSN, and diagnosis code;
- whether the drug has previously been prescribed and dispensed, if known, and whether the inability to obtain the drug poses an unreasonable risk of a medical emergency; and
- how the prescription treats the diagnosis, promotes recovery, or enhances the ability of the injured employee to return to or retain employment.

Medical emergency

The sudden onset of a medical condition manifested by acute symptoms of sufficient severity, including severe pain that in the absence of immediate medical attention could reasonably be expected to result in:

- placing the patient's health or bodily functions in serious jeopardy; or
- serious dysfunction of any body organ or part...

Includes Texas Occupations Code definitions for:

- Compounding
- Generic Equivalent
 - Pharmaceutically
 - Therapeutically
- Substitution
- Prescribing doctor (includes dentists, physician assistants, and advanced practice nurses)

§134.506 Outpatient Open Formulary for Claims with Dates of Injury Prior to September 1, 2011

(Open Formulary for Legacy Claims)

Effective January 17, 2011

Open Formulary for Legacy Claims

- Applies to both network and non-network claims with dates of injury prior to September 1, 2011.
- A legacy claim is any date of injury prior to September 1, 2011.
- Subject to the <u>open formulary</u> until September 1, 2013.

Open Formulary for Legacy Claims

How are drugs prescribed in an open formulary?

Non-Network

 According to the ODG treatment guidelines.

Network

 According to the certified network's treatment guidelines.

Open Formulary for Non-Network Claims

- Drugs included in an open formulary do not require preauthorization but are subject to retrospective review.
- However, investigational or experimental drugs statutorily require preauthorization.

Open Formulary for Non-Network Claims

 As of January 17, 2011 preauthorization is not required for drugs not recommended by the Official Disability Guidelines.

 (unless experimental or investigational)

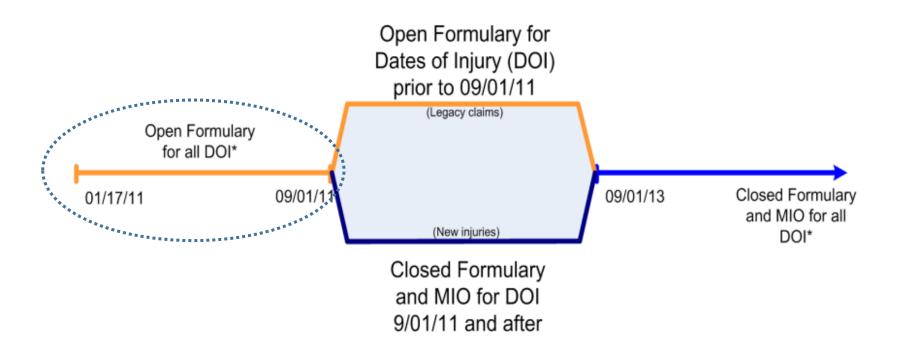
However they are subject to retrospective

However, they are subject to retrospective review.

Open Formulary for Network Claims

- Drugs in the open formulary shall be prescribed according to the certified network's treatment guidelines.
- Drugs prescribed and dispensed shall be preauthorized in accordance Texas Insurance Code Chapter 1305 and Texas Administrative Code Chapter 10.

Timeline of the Closed Formulary Implementation



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*Except Old Law Claims (DOI Dec 31, 1990 and before)



§134.510 Transition to the Use of the Closed Formulary for Claims with Dates of Injury Prior to September 1, 2011

(Transition of Legacy Claims)



New rule

- Addresses the transition of the legacy claims into a closed formulary.
- Applies to claims with dates of injury prior to September 1, 2011, which are subject to the closed formulary and the MIO process on or after September 1, 2013.

At any time between September 1, 2011 and September 1, 2013:

The prescribing doctor should include a statement of medical necessity with the prescription for drugs excluded from the closed formulary for legacy claims.

To facilitate the transition, the prescribing doctor or the insurance carrier may:

- Contact each other to discuss ongoing pharmacological management of the injured employee's claim.
- When the parties contact each other, they must provide a name, phone number, date, and time to discuss ongoing pharmacological management of the injured employee's claim.

Beginning no later than March 1, 2013, the insurance carrier shall:

- Identify legacy claims where an excluded drug has been prescribed after September 1, 2012.
- Provide written notification to the injured employee, prescribing doctor and pharmacy, if known.

The written notification will contain:

- Date the closed formulary will apply.
- Name, telephone number, and date and time to discuss ongoing pharmacological management of the injured employee's claim.

Agreement:

During the discussion, the insurance carrier and a prescribing doctor may enter into an agreement on the application of the closed formulary on an individual claim-by-claim basis.

Agreement requirements:

 Must be documented by the carrier and shared with the prescribing doctor and injured employee.

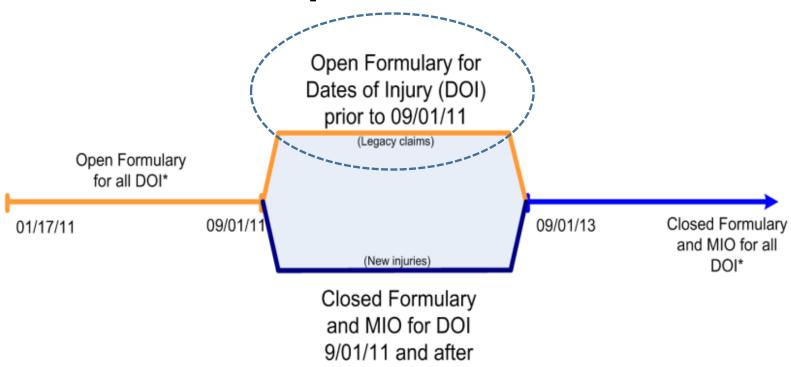
 Health care provided as a result of the agreement is not subject to retrospective review.

If an agreement is not reached:

• A denial of a request for an agreement is not subject to dispute resolution.

 Closed formulary applies as of September 1, 2013.

Timeline of the Closed Formulary Implementation



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Applicability of the Closed Formulary

§134.520 Outpatient Closed Formulary for Dates of Injury On or After September 1, 2011

• Formally adopts a closed formulary for dates of injury and after September 1, 2011.

§134.530 - Requirements for Use of the Closed Formulary for Claims Not Subject to Certified Networks

§134.540 - Requirements for Use of the Closed Formulary for Claims Subject to Certified Networks

Closed Formulary For Outpatient Use

Non-network

§134.530 (a)

Applies to nonnetwork claims on and after September 1, 2011.

Date of injury occurred on or after September 1, 2011.

Network

§134.540 (a)

Applies to network claims on and after September 1, 2011.

Date of injury occurred on or after September 1, 2011.

Closed Formulary and Preauthorization

Closed Formulary and Preauthorization

Non-network

Rule 134.530 (b)

Preauthorization is only required for :

- a) "N" status drugs
- b) Compounds containing "N" status drugs
- c) Experimental or investigational drugs as defined in Labor Code §413.014(a)

Network

Rule 134.540 (b)

Preauthorization is only required for:

- a) "N" status drugs
- b) Compounds containing "N" status drugs
- c) Experimental or investigational drugs as defined in Labor Code §413.014(a)

Pharmaceutical Benefits

TIC Chapter §4201 Utilization Review Agents

- §4201.101 CERTIFICATE OF REGISTRATION REQUIRED. A utilization review agent *may not* conduct utilization review unless the commissioner issues a certificate of registration to the agent under this subchapter.
- §4201.054 WORKERS' COMPENSATION BENEFITS. A workers' compensation insurance company *must* comply with TIC Chapter 4201 when performing utilization review.

Closed Formulary and Pain Pumps

Non-network

Rule 134.530 (c)(1)

Intrathecal drug delivery systems (pain pump) requires preauthorization.

In accordance with 134.600 and the request must include:

- 1. Regime plan of care, and
- 2. Anticipated dosage or range of dosages.

Network

Rule 134.540 (c)(1)

Intrathecal drug delivery systems (pain pump) requires preauthorization.

In accordance with the certified network's processes.

Closed Formulary and Pain Pumps

Non-network

Rule 134.530 (c)(2)

Refills of pain pump with drugs excluded from the closed formulary must be preauthorized on an annual basis.

Preauthorization is required in addition to annual preauth:

- 1. Change in the medications, dosages or drug regime.
- 2. Change in prescribing doctor.

Network

Rule 134.540 (c)(2)

Refills of pain pump with drugs excluded from the closed formulary must be preauthorized on an annual basis.

Preauthorization is required in addition to annual preauth:

- 1. Change in the medications, dosages or drug regime
- 2. Change in prescribing doctor.

Closed Formulary and Treatment Guidelines

Closed Formulary and Treatment Guidelines

Non-network

Rule 134.530 (d)(1-2)

Drugs shall be prescribed and dispensed according to ODG.

Drugs included in the formulary may be prescribed and dispensed without preauthorization when:

- 1. Recommended by ODG
- 2. Exceeds or not addressed by ODG

Network

Rule 134.540 (d)

Drugs shall be prescribed and dispensed according to the network's processes.

Closed Formulary and Treatment Guidelines

Non-network

Rule 134.530 (d)(3)

Drugs included in the closed formulary that are prescribed and dispensed without preauthorization:

 Are subject to retrospective review.

Network

Rule 134.540 (d)

Drugs included in the closed formulary that are prescribed and dispensed without preauthorization:

 Are subject to retrospective review.

Appeals for Drugs Excluded from the Closed Formulary

Non-network

Rule 134.530 (e)(1)

When a prescribing doctor determines and documents a need for an excluded drug and has prescribed the drug:

The prescribing doctor, injured employee, or other requestor

must request preauthorization.

Network

Rule 134.540 (e)(1)

When a prescribing doctor determines and documents a need for an excluded drug and has prescribed the drug:

The prescribing doctor, injured employee, or other requestor

 must request preauthorization.

Non-network

Rule 134.530 (e)(1)

Preauthorization must be in accordance with:

Rule 134.600
Preauthorization,
Concurrent Review and
Voluntary Certification of
Health Care

Network

Rule 134.540 (e)(1)

Preauthorization must be in accordance with:

Certified network's preauthorization process

Non-network

Rule 134.530 (e)(2)

If preauthorization is requested by the injured employee or other requestor and they request a statement of medical necessity:

 the prescribing doctor shall provide as set forth in §134.502

Network

Rule 134.540 (e)(2)

If preauthorization is requested by the injured employee or other requestor and they request a statement of medical necessity:

 the prescribing doctor shall provide as set forth in §134.502

Non-network

Rule 134.530 (e)(3)

If the preauthorization for an excluded drug is denied:

The requestor may submit a request for medical dispute resolution according to §133.308 MDR by Independent Review Organization

Network

Rule 134.540 (e)(3)

If the preauthorization for an excluded drug is denied:

The requestor may submit a request for medical dispute resolution according to §133.308 MDR by Independent Review Organization

Non-network

Rule 134.530 (e)(4)

In the event of an unreasonable risk of a medical emergency:

An interlocutory order may be obtained according to

- 1. §133.306 Interlocutory Orders for Medical Benefits; or
- 2. §134.550 Medical Interlocutory Order

Network

Rule 134.540 (e)(4)

In the event of an unreasonable risk of a medical emergency:

An interlocutory order may be obtained according to

- 1. §133.306 Interlocutory Orders for Medical Benefits; or
- 2. §134.550 Medical Interlocutory Order

Closed Formulary and Initial Pharmaceutical Coverage

Initial Pharmaceutical Coverage Texas Labor Code §413.0141

...an insurance carrier shall provide for payment of specified pharmaceutical services sufficient for the first seven days following the date of injury:

- if the health care provider requests and receives verification of insurance coverage, and
- a verbal confirmation of an injury from the employer or from the insurance carrier...

Closed Formulary and Initial Pharmaceutical Coverage

Non-network

Rule 134.530 (f)(1)

Drugs *included* in the closed formulary may be prescribed and dispensed without preauthorization:

 Are not subject to retrospective review.

Network

Rule 134.540 (f)(1)

Drugs *included* in the closed formulary may be prescribed and dispensed without preauthorization:

 Are not subject to retrospective review.

Closed Formulary and Initial Pharmaceutical Coverage

Non-network

Rule 134.530 (f)(2)

Drugs excluded from the closed formulary may be prescribed and dispensed without preauthorization, except for experimental or investigational drugs:

 Are subject to retrospective review.

Network

Rule 134.540 (f)(2)

Drugs *excluded* from the closed formulary may be prescribed and dispensed without preauthorization:

 Are subject to retrospective review.

Non-network

Rule 134.530 (g)&(g)(1)

Drugs that do not require preauthorization are subject to retrospective review.*

Drugs provided in accordance with ODG are presumed reasonable and reasonably required.

*except those prescribed under rule for initial pharmaceutical coverage

Network

Rule 134.540 (g)

Drugs that do not require preauthorization are subject to retrospective review.*

*except those prescribed under rule for initial pharmaceutical coverage



Non-network

Rule 134.530 (g)(2)

In order for an insurance carrier to deny payment subject to retrospective review for a drug recommended by ODG:

The denial must be supported by documentation of evidence-based medicine that outweighs the presumption of reasonableness.

Network

Rule 134.540 (g)(1)

In order for a carrier to deny payment subject to retrospective review for a drug that is within the certified network treatment guidelines:

The denial must be supported by documentation of evidence -based medicine that outweighs the network treatment guidelines.

Non-network

Rule 134.530 (g)(3)

Prescribing doctor who prescribes drugs that exceed, are not recommended or are not addressed by the ODG.

Must provide a statement of medical necessity upon request.

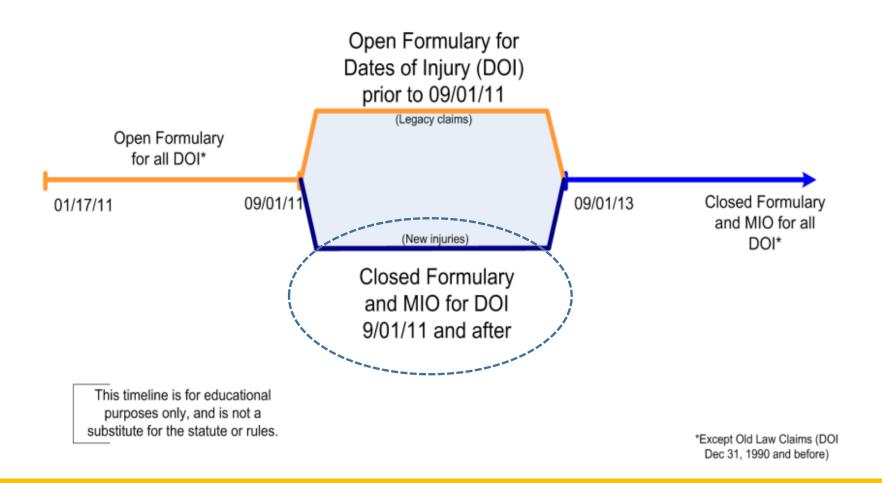
Network

Rule 134.540 (g)(2)

Prescribing doctor who prescribes drugs that exceed, are not recommended or are not addressed by the certified network treatment guidelines must:

Must provide a statement of medical necessity upon request.

Timeline of the Closed Formulary Implementation



§134.502 Pharmaceutical Services

Statement of Medical Necessity

§134.502 Pharmaceutical Services

The carrier, employee, or pharmacist may request a statement of medical necessity from the prescribing doctor.

Statement of Medical Necessity

§134.502 Pharmaceutical Services

The prescribing doctor shall provide a statement of medical necessity to the requesting party:

- not later than the 14th working day after receipt of request; and
- shall not bill for nor shall the carrier reimburse for the statement of medical necessity.

§134.550 Medical Interlocutory Order (MIO)

Medical Interlocutory Order (MIO)

When the preauthorization denial of a drug excluded from the closed formulary:

- poses an unreasonable risk of medical emergency to the injured employee,
- provides a means for an injured employee to continue use of the previously prescribed and dispensed drug(s) throughout the duration of the appeals/dispute process.

Medical Interlocutory Order

Who can submit a request for an MIO?

- Pharmacy
- Prescribing doctor

Requests for an interlocutory order that do not meet these criteria can be requested through §133.306.

Medical Interlocutory Order

Medical Interlocutory Order will be issued if the request contains the following information:

- 1. injured employee name;
- 2. date of birth of injured employee;
- 3. prescribing doctor's name;
- 4. name of drug and dosage;
- MIO requestor's name (pharmacy or prescribing doctor);
- 6. MIO requestor's contact information;

Medical Interlocutory Order continued...

Additional Criteria

- 7. The preauthorization request for a previously prescribed and dispensed drug(s), which is excluded from the closed formulary, has been denied by the insurance carrier;
- 8. Has submitted an independent review (IRO) to the insurance carrier or the insurance carrier's utilization review agent;

Medical Interlocutory Order continued...

Additional Criteria

- 9. Noted that the preauthorization denial poses an unreasonable risk of a medical emergency (as defined in §134.500);
- 10. Have identified the potential of an unreasonable risk of medical of emergency has been documented in the preauthorization request;
- 11. Notified the insurance carrier that a request for an MIO is being submitted to DWC; and

Medical Interlocutory Order continued ...

12. a signature and the following certification by the MIO requestor:

"I hereby certify under penalty of law that the previously listed conditions have been met."

Medical Interlocutory Order

Submit the request for MIO to DWC and copy:

- Prescribing doctor
- Injured employee
- Dispensing Pharmacy (if known)
- Insurance Carrier

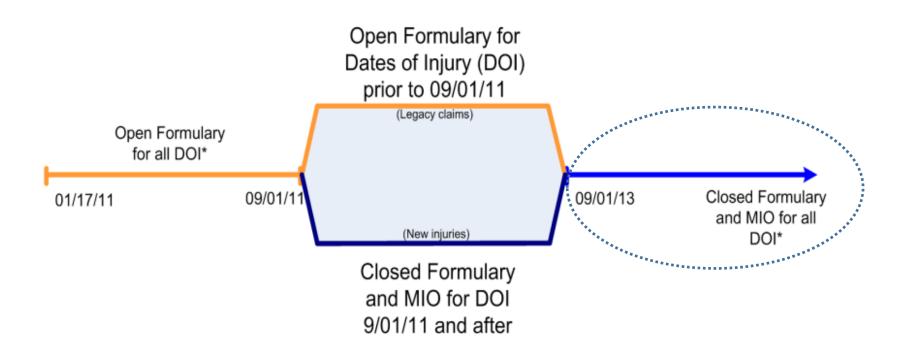
The full details of the dispute process are provided in the rule and include opportunities to appeal Independent Review Organizations (IRO) decisions to a Contested Case Hearings (CCH) and district court in accordance with DWC rules.

§133.306 Interlocutory Orders for Medical Benefits

Interlocutory Orders (IO)

- Allows DWC to issue interlocutory orders for accrued and/or future medical benefits;
- Allows for an injured employee to request an IO when an insurance carrier makes an adverse determination for an excluded drug (prescribed on or after September 1, 2011); and
- DWC determines those medical benefits are or were medically necessary and constitute health care reasonably required.

Timeline of the Closed Formulary Implementation



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Case Scenarios

Date of injury: 09-15-2011

Date of scripts: 10-01-2011

Date of dispense: 10-02-2011

Drugs: Three prescription drugs; two are included in the closed formulary and the third drug is excluded from the closed formulary with an "N" status.

- 1. Does the closed formulary apply to the claim?
- 2. Is preauthorization required for any of the drugs?

Date of injury: 08-15-2009

Date of script: 02-24-2012

Date of dispense: 02-25-2012

Drug: One drug that is excluded from the closed formulary with an "N" status.

1. Does the closed formulary apply to the claim?

2. Is preauthorization required for the drug?

Date of injury: 08-15-2011

Date of script: 10-02-2013

Date of dispense: 10-03-2013

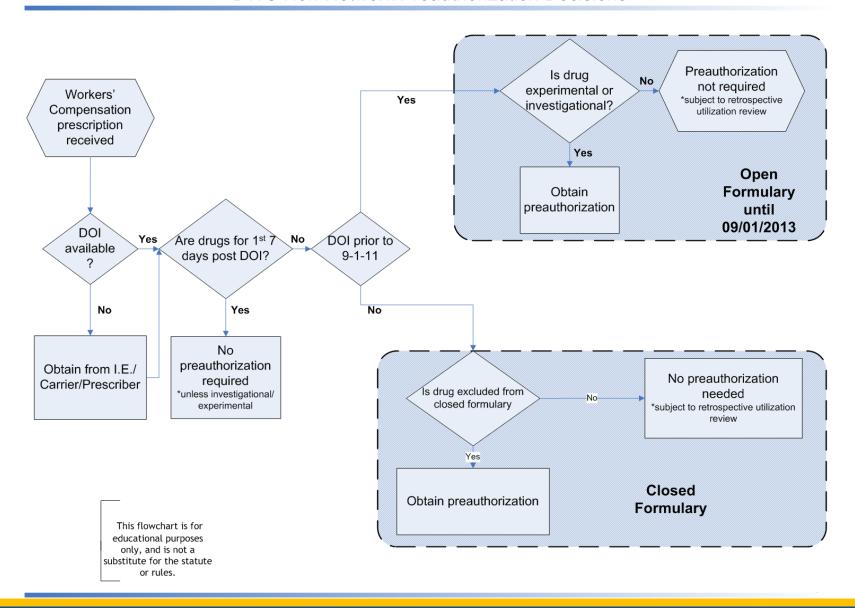
Drug: One drug that is excluded from the closed formulary with an "N" status.

Scenario #3 - Answers

1. Does the closed formulary apply to the claim?

2. Is preauthorization required for the drug?

DWC Non-Network Preauthorization Decisions



Topics Covered

Texas Department of Insurance, Division of Workers' Compensation Overview

Pharmacy Formulary Rule History & Development

Pharmacy Closed Formulary Amended and New Rules

Case Scenarios and Resources

Resources

Web Resources

Official Disability Guidelines (ODG)

(Non-Network treatment guidelines and ODG Appendix A) www.mcg.com/odg/

ODG Texas Workers' Compensation Status "N" Drugs

www.tdi.texas.gov//wc/pharmacy/index.html

Web Resources

Pharmacy webpage

www.tdi.texas.gov//wc/pharmacy/index.html

Health care provider training and resources web page

www.tdi.texas.gov//wc/hcprovider/index.html

Call or email



Injured Employee Resources

The Office of Injured Employee Counsel (OIEC) is the state agency that can assist injured employees with their workers' compensation claims.

OIEC contact:

1-866-EZE-OIEC (1-866-393-6432) www.oiec.texas.gov

