Pharmacy Closed Formulary Rules

This presentation is for educational purposes only and is not a substitute for the statute and Division rules.
Topics Covered

• Texas Department of Insurance Overview

• Pharmacy Formulary Rule History & Development

• Pharmacy Formulary Rules

• Case Scenarios and Resources
Topics Covered

Pharmacy Formulary Rules

- Amended §134.500
- Amended §134.506
- New §134.510
- New §134.520
- New §134.530
- New §134.540
- New §134.550
- Amended §133.306

Can be found under “Adoptions”

http://www.tdi.texas.gov/wc/rules/index.html

- Existing §134.502
Workers' Compensation Rules

28 Texas Administrative Code (TAC) Chapters 102 - 180 (for injuries on or after January 1, 1991)
- Rules in HTML format (Secretary of State website)
- Rules in PDF format (TDI)

Adoptions
- Adoptions
- Rulebook Supplements
  - Rulebook Supplement 2011-01 Available Online
  - How To Update Your Rulebook

Proposals
- Proposed Rules for Public Comment
- Informal Working Draft Rules for Comment

Resources
- Texas Register (official repository of state rules and open meetings information)
- Certified Workers' Compensation Network Rules (28 TAC Chapter 10)
- TDI-DWC Rule Chart (PDF)
- HB 7 Related Rule Projects
- Webcast Archive (audio files from public hearings and stakeholder meetings)
- Old Law Rules: 28 TAC Chapters 41-89 (for injuries prior to January 1, 1991)
Who is the 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 TDI-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 Divisions

Division of Workers’ Compensation (DWC)
  • Non Network Claims
  • Political Subdivisions

Health and Workers’ Compensation Certified Networks Division (HWCN)
  • Certified Workers’ Compensation Network Claims
  • Political Subdivisions that formed a certified network
Office of Injured Employee Counsel (OIEC)

• Provides injured employee assistance

• Office of Injured Employee Counsel (OIEC) by calling the toll-free telephone number

• 1-866-EZE-OIEC (1-866-393-6432)

  www.oiec.texas.gov
Texas Workers’ Compensation Regulation
The Texas Insurance Code

Website Information

Rules Chapters §§1-34:
§10 Networks, §12 IRO, §19 URA
(Texas Administrative Code)

Texas Insurance Code
The Act (Law) §§30-7002
§1305 WC Certified Networks, § 4201 URA and
§4202 IRO
The Texas Labor Code

Website Information

Texas Labor Code
The Act (Law)
§§401-506

Rules
§§100-180
(Texas Administrative Code)

Information
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 Closed Formulary
Amended and New Rules
History of Rule 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.”
History of Rule Development

The TDI-DWC:

Conducted stakeholder meetings

• August 2008
• March 2009
• August 2009

Posted 3 informal working drafts of the rules prior to formal proposal

• December 16, 2008
• June 12, 2009
• February 4, 2010
History of Rule Development

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
History of Rule Development

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*
Pharmacy Formulary Rules

28 TAC Chapter 134  Benefits—Guidelines for Medical Services, Charges and Payments

Subchapter F, Pharmaceutical Benefits
Pharmacy Formulary Rules

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”
Pharmacy Formulary Rules

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
Pharmacy Formulary Rules

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
Pharmacy Formulary Rules

New Rules

§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
§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

Open Formulary for Dates of Injury (DOI) prior to 09/01/11

Open Formulary for all DOI*

01/17/11

09/01/11

(Legacy claims)

(Closed Formulary and MIO for DOI 9/01/11 and after)

09/01/13

Closed Formulary and MIO for all DOI*

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

This timeline is for educational purposes only, and is not a substitute for the statute or rules.
§134.500
Definitions
Definitions

Defines “Closed Formulary” as:

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

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 compounded drugs that contains a drug identified with an “N” status in ODG; and
- investigational or experimental drugs as defined in Texas Labor Code §413.014(a)
Closed Formulary includes ALL FDA approved drugs

- **Needs Preauth***
- Investigational or Experimental Drugs
- Drugs w/ status “N”
- Compounds that contain drugs w/ status “N”

*after initial pharmaceutical coverage*
“N” Status Drugs

• ODG’s appendix A is the most current publication for “N” status drugs: www.worklossdata.com

• TDI-DWC will post the “N” status drugs from ODG’s Appendix A on its website: http://www.tdi.texas.gov/wc/pharmacy/index.html

• “N” status drugs is updated monthly
## ODG Workers’ Compensation Drug Formulary

<table>
<thead>
<tr>
<th>Drug Class</th>
<th>Generic Name</th>
<th>Brand Name</th>
<th>GE</th>
<th>Status</th>
<th>Cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>Opioids</td>
<td>Codeine</td>
<td>Codeine</td>
<td>Y</td>
<td>Y</td>
<td></td>
</tr>
<tr>
<td>Opioids</td>
<td>Codeine/acetamin.</td>
<td>Tylenol #3</td>
<td>Y</td>
<td>Y</td>
<td>$2.81</td>
</tr>
<tr>
<td>Opioids</td>
<td>Fentanyl buccal</td>
<td>Fentora®</td>
<td>N</td>
<td>N</td>
<td></td>
</tr>
<tr>
<td>Opioids</td>
<td>Fentanyl buccal film</td>
<td>Onsolis™</td>
<td>N</td>
<td>N</td>
<td></td>
</tr>
<tr>
<td>Opioids</td>
<td>Fentanyl lollipop</td>
<td>Actiq®</td>
<td>Y</td>
<td>N</td>
<td>$1,516.13</td>
</tr>
<tr>
<td>Opioids</td>
<td>Fentanyl transdermal</td>
<td>Duragesic®</td>
<td>Y</td>
<td>Y</td>
<td>$160.38</td>
</tr>
<tr>
<td>Opioids</td>
<td>Fentanyl transmucosal</td>
<td>Abstral</td>
<td>N</td>
<td>N</td>
<td></td>
</tr>
<tr>
<td>Opioids</td>
<td>Hydrocodone/acetamin.</td>
<td>Vicodin®</td>
<td>Y</td>
<td>Y</td>
<td>$21.79</td>
</tr>
</tbody>
</table>

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http://www.tdi.texas.gov/wc/dm/index.html

Disability Management News & Publications

- Monthly Listing of “N” Drugs in Official Disability Guidelines – Treatment in Workers’ Comp (ODG) / Appendix A, ODG Workers’ Compensation Drug Formulary (PDF)
  - "N" Drug List (Excel)
- Monthly Updates to Official Disability Guidelines - Memo (PDF); Spreadsheet (Excel, PDF)
# 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).

**ODG Texas Workers’ Compensation Status "N" Drugs**
(Excluded from the Closed Formulary as of March 31, 2011)

<table>
<thead>
<tr>
<th>Drug Class</th>
<th>Generic Name</th>
<th>Brand Name</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Opioids</td>
<td>Buprenorphine (for pain)</td>
<td>Suboxone®</td>
<td>N</td>
</tr>
<tr>
<td>Opioids</td>
<td>Buprenorphine (transdermal)</td>
<td>Butrans™</td>
<td>N</td>
</tr>
<tr>
<td>Opioids</td>
<td>Butalbital</td>
<td>Fioricet®</td>
<td>N</td>
</tr>
<tr>
<td>Opioids</td>
<td>Fentanyl buccal</td>
<td>Fentora®</td>
<td>N</td>
</tr>
<tr>
<td>Opioids</td>
<td>Fentanyl buccal film</td>
<td>Onsolis™</td>
<td>N</td>
</tr>
<tr>
<td>Opioids</td>
<td>Fentanyl lollipop</td>
<td>Actiq®</td>
<td>N</td>
</tr>
<tr>
<td>Opioids</td>
<td>Fentanyl transmucosal</td>
<td>Abstral</td>
<td>N</td>
</tr>
<tr>
<td>Opioids</td>
<td>Hydrocodone/ibuprofen</td>
<td>Vicoprofen®</td>
<td>N</td>
</tr>
<tr>
<td>Opioids</td>
<td>Hydromorphone ER</td>
<td>Exalgo</td>
<td>N</td>
</tr>
<tr>
<td>Opioids</td>
<td>Meperidine</td>
<td>Demerol®</td>
<td>N</td>
</tr>
<tr>
<td>Opioids</td>
<td>Methadone (link to rules)</td>
<td>Methadose®</td>
<td>N</td>
</tr>
<tr>
<td>Opioids</td>
<td>Morphine ER</td>
<td>Avinza®</td>
<td>N</td>
</tr>
<tr>
<td>Opioids</td>
<td>Morphine ER</td>
<td>Kadian®</td>
<td>N</td>
</tr>
<tr>
<td>Opioids</td>
<td>Oxycodone</td>
<td>OxyContin®</td>
<td>N</td>
</tr>
</tbody>
</table>
Definitions

Defines “Open formulary” as:

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 non-drug items.
Definitions

Statement of medical necessity is:

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.
Definitions

Statement of medical necessity shall 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
Definitions

Statement of medical necessity shall include:

• how the prescription treats the diagnosis, promotes recovery, or enhances the ability of the injured employee to return to or retain employment
Definitions

Medical emergency is defined as:
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
Definitions

Also includes other definitions, which are defined in the Texas Occupations Code:

- 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
(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 open formulary 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

- However, they are subject to retrospective review

*unless experimental or investigational
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 with Texas Insurance Code Chapter 1305 and Texas Administrative Code Chapter 10.
Timeline of the Closed Formulary Implementation

Open Formulary for Dates of Injury (DOI) prior to 09/01/11

Open Formulary for all DOI*

01/17/11

09/01/11

(Legacy claims)

09/01/13

Closed Formulary and MIO for DOI 9/01/11 and after

Closed Formulary and MIO for all DOI*

This timeline is for educational purposes only, and is not a substitute for the statute or rules.

*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
Transition of Legacy Claims

- 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
Transition of Legacy Claims

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.
Transition of 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
Transition of Legacy Claims

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
Transition of Legacy Claims

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
Transition of Legacy Claims

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.
Transition of Legacy Claims

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
Transition of Legacy Claims

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

Open Formulary for Dates of Injury (DOI) prior to 09/01/11

(Legacy claims)

Open Formulary for all DOI*

01/17/11

09/01/11

09/01/13

Closed Formulary and MIO for DOI 9/01/11 and after

Closed Formulary and MIO for all DOI*

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

This timeline is for educational purposes only, and is not a substitute for the statute or rules.
§134.520  Outpatient Closed Formulary for Dates of Injury On or After September 1, 2011

Formally adopts a closed formulary for dates of injury on or after September 1, 2011
§134.530 - Requirements for Use of the Closed Formulary for Claims Not Subject to Certified Networks

AND

§134.540 - Requirements for Use of the Closed Formulary for Claims Subject to Certified Networks
Applicability of the Closed Formulary
# Closed Formulary For Outpatient Use

<table>
<thead>
<tr>
<th>Non-Network</th>
<th>Network</th>
</tr>
</thead>
<tbody>
<tr>
<td>§134.530 (a) applies to <em>non-network</em> claims on and after September 1, 2011</td>
<td>§134.540 (a) applies to <em>network</em> claims on and after September 1, 2011</td>
</tr>
<tr>
<td>date of injury occurred on or after September 1, 2011</td>
<td>date of injury occurred on or after September 1, 2011</td>
</tr>
</tbody>
</table>
Closed Formulary and Preauthorization
# Closed Formulary For Outpatient Use

<table>
<thead>
<tr>
<th>Non-Network</th>
<th>Network</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Rule 134.530 (b)</strong></td>
<td><strong>Rule 134.540 (b)</strong></td>
</tr>
<tr>
<td>Preauthorization is only required for:</td>
<td>Preauthorization is only required for:</td>
</tr>
<tr>
<td>a) “N” status drugs</td>
<td>a) “N” status drugs</td>
</tr>
<tr>
<td>b) Compounds containing “N” status drugs</td>
<td>b) Compounds containing “N” status drugs</td>
</tr>
<tr>
<td>c) Experimental or investigational drugs as</td>
<td>c) Experimental or investigational drugs as</td>
</tr>
<tr>
<td>defined in Labor Code §413.014(a)</td>
<td>defined in Labor Code §413.014(a)</td>
</tr>
</tbody>
</table>

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
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

<table>
<thead>
<tr>
<th>Non-Network</th>
<th>Network</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Rule 134.530 (c)(2)</strong></td>
<td><strong>Rule 134.540 (c)(2)</strong></td>
</tr>
<tr>
<td>Refills of pain pump with drugs excluded from the closed formulary must be preauthorized on an annual basis</td>
<td>Refills of pain pump with drugs excluded from the closed formulary must be preauthorized on an annual basis</td>
</tr>
<tr>
<td>Preauthorization is required in addition to annual preauth:</td>
<td>Preauthorization is required in addition to annual preauth:</td>
</tr>
<tr>
<td>1. Change in the medications, dosages or drug regime</td>
<td>1. Change in the medications, dosages or drug regime</td>
</tr>
<tr>
<td>2. Change in prescribing doctor</td>
<td>2. Change in prescribing doctor</td>
</tr>
</tbody>
</table>
Closed Formulary and Treatment Guidelines
## Closed Formulary and Treatment Guidelines

<table>
<thead>
<tr>
<th>Non-Network</th>
<th>Network</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rule 134.530 (d)(1-2)</td>
<td>Rule 134.540 (d)</td>
</tr>
<tr>
<td>Drugs shall be prescribed and dispensed according to ODG</td>
<td>Drugs shall be prescribed and dispensed according to the network’s processes</td>
</tr>
<tr>
<td>Drugs included in the formulary may be prescribed and dispensed without preauthorization when:</td>
<td></td>
</tr>
<tr>
<td>1. Recommended by ODG</td>
<td></td>
</tr>
<tr>
<td>2. Exceeds or not addressed by ODG</td>
<td></td>
</tr>
</tbody>
</table>
# Closed Formulary and Treatment Guidelines

<table>
<thead>
<tr>
<th>Non-Network</th>
<th>Network</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Rule 134.530 (d)(3)</strong></td>
<td><strong>Rule 134.540 (d)</strong></td>
</tr>
<tr>
<td>Drugs included in the closed formulary that are prescribed and dispensed without preauthorization:</td>
<td>Drugs included in the closed formulary that are prescribed and dispensed without preauthorization:</td>
</tr>
<tr>
<td>• Are subject to retrospective review</td>
<td>• Are subject to retrospective review</td>
</tr>
</tbody>
</table>
Appeals for Drugs Excluded from the Closed Formulary
## Closed Formulary and Appeals

<table>
<thead>
<tr>
<th>Non-Network</th>
<th>Network</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Rule 134.530 (e)(1)</strong></td>
<td><strong>Rule 134.540 (e)(1)</strong></td>
</tr>
<tr>
<td>When a prescribing doctor determines and documents a need for an excluded drug and has prescribed the drug:</td>
<td>When a prescribing doctor determines and documents a need for an excluded drug and has prescribed the drug:</td>
</tr>
<tr>
<td>The prescribing doctor, injured employee, or other requestor</td>
<td>The prescribing doctor, injured employee, or other requestor</td>
</tr>
<tr>
<td>• must request preauthorization</td>
<td>• must request preauthorization</td>
</tr>
</tbody>
</table>
## Closed Formulary and Appeals

<table>
<thead>
<tr>
<th>Non-Network</th>
<th>Network</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rule 134.530 (e)(1)</td>
<td>Rule 134.540 (e)(1)</td>
</tr>
<tr>
<td>Preauthorization must be in accordance with:</td>
<td>Preauthorization must be in accordance with:</td>
</tr>
<tr>
<td>Rule 134.600</td>
<td>Certified network’s preauthorization process</td>
</tr>
</tbody>
</table>
| Preauthorization, Concurrent Review and Voluntary Certification of Health Care | }
## Closed Formulary and Appeals

<table>
<thead>
<tr>
<th>Non-Network</th>
<th>Network</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Rule 134.530 (e)(2)</strong>&lt;br&gt;If preauthorization is requested by the injured employee or other requestor and they request a statement of medical necessity:&lt;br&gt;• the prescribing doctor shall provide as set forth in §134.502</td>
<td><strong>Rule 134.540 (e)(2)</strong>&lt;br&gt;If preauthorization is requested by the injured employee or other requestor and they request a statement of medical necessity:&lt;br&gt;• the prescribing doctor shall provide as set forth in §134.502</td>
</tr>
</tbody>
</table>
### Closed Formulary and Appeals

<table>
<thead>
<tr>
<th>Non-Network</th>
<th>Network</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Rule 134.530 (e)(3)</strong></td>
<td><strong>Rule 134.540 (e)(3)</strong></td>
</tr>
<tr>
<td>If the preauthorization for an excluded drug is denied:</td>
<td>If the preauthorization for an excluded drug is denied:</td>
</tr>
<tr>
<td>The requestor may submit a request for medical dispute resolution according to §133.308 MDR by Independent Review Organization</td>
<td>The requestor may submit a request for medical dispute resolution according to §133.308 MDR by Independent Review Organization</td>
</tr>
</tbody>
</table>
## Closed Formulary and Appeals

<table>
<thead>
<tr>
<th><strong>Non-Network</strong></th>
<th><strong>Network</strong></th>
</tr>
</thead>
</table>
| **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 | **Rule 134.540 (e)(4)**  
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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 Coverage

<table>
<thead>
<tr>
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Closed Formulary and Retrospective Review
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<td>Drugs that do not require preauthorization are subject to retrospective review*</td>
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<td>Drugs provided in accordance with ODG are presumed reasonable and reasonably required</td>
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<td><strong>Rule 134.530 (g)(2)</strong>&lt;br&gt;In order for an insurance carrier to deny payment subject to retrospective review for a drug recommended by ODG:</td>
<td><strong>Rule 134.540 (g)(1)</strong>&lt;br&gt;In order for a carrier to deny payment subject to retrospective review for a drug that is <em>within the certified network treatment guidelines</em>:</td>
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<td>The denial must be supported by documentation of evidence-based medicine that outweighs the presumption of reasonableness</td>
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## Closed Formulary and Retrospective Review

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*Except Old Law Claims (DOI Dec 31, 1990 and before)
§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;
5. 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;
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 emergency has been documented in the preauthorization request;

11. Notified the insurance carrier that a request for an MIO is being submitted to the division; 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 the Division 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 Division rules.
§133.306
Interlocutory Orders
for
Medical Benefits
Interlocutory Orders (IO)

Allows the Division to issue interlocutory orders for accrued and/or future medical benefits
Interlocutory Orders (IO)

- 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

- Division determines those medical benefits are or were medically necessary and constitute health care reasonably required
Timeline of the Closed Formulary Implementation

Open Formulary for Dates of Injury (DOI) prior to 09/01/11

Open Formulary for all DOI*

01/17/11

Closed Formulary and MIO for DOI 9/01/11 and after

09/01/11

09/01/13

Closed Formulary and MIO for all DOI*

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Case Studies
Scenario #1

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?
Scenario #2

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.
Scenario #2

1. Does the closed formulary apply to the claim?

2. Is preauthorization required for the drug?
Scenario #3

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

Workers' Compensation prescription received

- DOI available?
  - Yes: Are drugs for 1st 7 days post DOI?
    - Yes: DOI prior to 9-1-11
      - Yes: Is drug experimental or investigational?
        - Yes: Obtain preauthorization
        - No: Preauthorization not required
          *subject to retrospective utilization review

- No: Obtain from I.E./Carrier/Prescriber

- No: Are drugs for 1st 7 days post DOI?
  - Yes: No preauthorization required
    *unless investigational/experimental
  - No: DOI prior to 9-1-11

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Topics Covered:

• TDI-DWC Overview
• Rule History and Development
• Pharmacy Formulary Rules
• Case Scenarios and Resources
Resources

Official Disability Guidelines
(Non-Network treatment guidelines and ODG Appendix A)

www.worklossdata.com
www.worklossdata.com/odgtraining.htm

ODG Texas Workers’ Compensation Status
“N” Drugs

www.tdi.texas.gov/wc/pharmacy
Resources

Pharmacy Closed Formulary Rules
(28 TAC Subchapter F Pharmaceutical Services)

General Information about Medical Services

800-372-7713
512-804-4000 (Austin Area)

Texas Department of Insurance, Division of Workers’ Compensation
Thank You!