Gabapentinoid Drug Use Evaluation

The Food and Drug Administration (FDA) issued a warning that serious, life-threatening, and fatal respiratory depression has been reported with the use of gabapentinoids (gabapentin and pregabalin). Most cases occur with co-administration of central nervous system (CNS) depressants, especially opioids, in the setting of underlying respiratory impairment or in the elderly. Respiratory depression was seen both with chronic use and acute use. Additional clinical information has been requested from manufacturers to help better assess the level of risk. For now, the FDA recommends that patients should start gabapentinoids at the lowest dose and should monitor for symptoms of respiratory depression when they are co-prescribed with an opioid or other agent that causes CNS depression.

The safety communication can be found here:

https://www.fda.gov/safety/medical-product-safety-information/neurontin-gralise-horizant-gabapentin-and-lyrica-lyrica-cr-pregabalin-drug-safety-communication.

When reviewing claims data from the fee-for-service population, it was noted that there were members who had one or more risk factors alongside therapy with a gabapentinoid. An educational intervention was planned as a result of the significant safety risk.

Intervention Summary

The following table shows a summary of the proposed intervention topics and the number of potential patients that may be targeted by each intervention. The number of potential patients is based on the most recent ICER. The actual number of targeted patients for each intervention will be based on the ICER for the month the intervention is performed.

Outcomes assessment will be completed 180 days after the intervention is performed.

Proposed Intervention Topic	MCO	Pediatric (Age 18 and below)	Adult
1. Patients (all ages) taking a gabapentinoid for 30 days in the last 90 days along with a CNS depressant for at least 15 days in the last 90 days.	**17,719**	**48**	**9**

Criteria Recommendation:

1. Gabapentinoids and Respiratory Depression
Alert Message: The FDA is warning that serious, life-threatening, and fatal respiratory depression has been reported with the use of gabapentinoids (gabapentin and pregabalin). Most cases occurred in association with co-administration central nervous system (CNS) depressants, especially opioids, in the setting of underlying respiratory impairment, or in the elderly. When co-prescribing gabapentinoids with another CNS depressant, particularly an opioid, or in patients with underlying respiratory impairment, initiate the gabapentinoid at the lowest dose and monitor for respiratory depression and sedation.

Population:
Patients (all ages) taking a gabapentinoid for 30 days in the last 90 days along with a CNS depressant for at least 15 days in the last 90 days.

MCO	FFS	Pediatric (Age 18 and below)
17,719	48	9

References:
FDA Drug Safety Communication: FDA warns about serious breathing problems with seizure and nerve pain medicines gabapentin (Neurontin, Gralise, Horizant) and pregabalin (Lyrica, Lyrica CR) when used with CNS depressants or in patients with lung problems.
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Facts & Comparisons, 2023 Updates, Wolters Kluwer Health.

TEXAS
Health and Human Services

[TODAY]

[adrs1]
[adrs2]
[adrs3]
[adrs4]

DEAR [tadrs1]:

In compliance with the OBRA '90 federal legislation, state Medicaid agencies are mandated to conduct Retrospective Drug Utilization Review Programs (RDUR). We hope that this retrospective DUR may assist you in optimizing your Medicaid patient's drug therapy. One way to achieve this goal is to identify potential drug therapy problems that may place patients at risk, particularly if multiple providers are identified. This RDUR program is informational in nature and allows you to incorporate the information provided into your continuing assessment of the patient's drug therapy requirements.

During a recent review of the enclosed drug history profile, *it was noted that your patient*, **[t1d0-recip-fst-nm] [t1d0-recip-lst-nm]**, *is receiving* **[drug_a_name]**. [alert_msg] The indicated condition has been inferred by the presence of **[drug_b_name]** in the patient's drug history. We routinely notify practitioners of such continued use by the patient to ensure that this regimen is still desired. The enclosed historical profile is provided for your evaluation and consideration. In presenting this information to you, we recognize that the management of each patient's drug therapy depends upon an assessment of the patient's entire clinical situation about which we are not fully aware. It is also possible that your license number may have been inadvertently assigned to the claim as an error at the pharmacy during the billing process. Some prescribed medications as well as some recommended laboratory monitoring or physical examinations may not appear on the patient's profile because they may have been privately purchased or were not billable to Medicaid Services.

The success of the DUR program is enhanced by the two way exchange of information. Therefore, at your convenience, we would appreciate learning of your assessment of this information and of any action taken in response to this notice. Although your participation in this program is voluntary, we find your feedback helpful in adjusting our program to address clinically important problems. We thank you for reviewing this information and caring for Texas Medicaid patients. *Please submit your response using the online provider response portal or complete the enclosed response form and fax it to (833) 470-0598. The online provider response portal can be accessed at https://forms.office.com/r/CXGEADqkRd or by scanning the QR code listed below.*

At the bottom of this letter are the specific prescriptions attributed to you by the dispensing pharmacy. In addition, if multiple prescribers are involved in the therapy mentioned above, each will receive this information. Thank you for your professional consideration.

RX #(s): [rx_no_a]

Sincerely,
Medicaid Drug Use Review Board

Administered by Kepro
PO Box 3570
Auburn, AL 36831
(800)225-6998 x3033 Fax (833) 470-0598

TEXAS
Health and Human Services

Case#: [case_no]
Enclosures

Administered by Kepro
PO Box 3570
Auburn, AL 36831
(800)225-6998 x3033 Fax (833) 470-0598

TEXAS
Health and Human Services

PRESCRIBER RESPONSE

All information used to generate the enclosed letter, including Prescriber identification, was obtained from Pharmacy Claims Data. If there appears to be an error in the information provided, please note the discrepancy. Thank you for your cooperation. *As a reminder, the response can be submitted using the online provider response portal. The online provider response portal can be accessed at https://forms.office.com/r/CXGEADqkRd or by scanning the QR code listed below.*

1. This patient **is** under my care:

_____ I have reviewed the information and will continue without change.
_____ however, I did not prescribe the following medication(s)_____.
_____ and has an appointment to discuss drug therapy.
_____ however, has not seen me recently.
_____ however, I was not aware of other prescribers.
_____ I have reviewed the information and modified drug therapy.
_____ I have not modified drug therapy because benefits outweigh the risks.
_____ I have tried to modify therapy, however the patient refuses to change.
_____ I have tried to modify therapy, however symptoms reoccurred.

2. This patient **is not** under my care:

_____ however, I did prescribe medication while covering for other MD or in the ER.
_____ but has previously been a patient of mine.
_____ because the patient recently expired.
_____ and has never been under my care.

3. I have reviewed the enclosed information and found it:
_____ very useful_____ useful_____ neutral_____ somewhat useful_____ not useful.

4. Please check here if you wish to receive reference information on the identified problem___.(Please provide a fax number if available_____-_____-_____.)

Comments:
_____
_____
_____

[adrs1] Case# [case_no]
Letter Type [letter_type]
[alert_msg]
[criteria]

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