

Medicaid Cutbacks Push Uninsured Into EDs

BY PATRICE WENDLING

Chicago Bureau

CHICAGO — Medicaid cutbacks in Tennessee were associated with an abrupt and sustained increase in emergency department use and hospital admission among the uninsured, research shows.

In August 2005, the state of Tennessee disenrolled approximately 171,000 individuals older than 18 years from TennCare, the state's Medicaid managed care program.

Between the predisenrollment period of Jan. 1, 2004, through July 31, 2005, and the postdisenrollment period of Aug. 1, 2005, through July 31, 2006, ED visits by the uninsured increased by 95,464, or 4.5%, and decreased among TennCare beneficiaries by 160,823, or 6%.

"This research shows that health policy decisions have real effects on the patients we see in America's emergency departments," said Dr. Benjamin S. Heavrin, who presented the study find-

ings at the annual meeting of the American College of Emergency Physicians. "The cost savings from disenrollment resulted in an increasing proportion of uninsured patients in Tennessee's EDs. This suggests an increasing financial burden on the newly uninsured and a possible ominous shift in their health status, based on our admission data."

The uninsured represented 12.7% of all patients in the EDs in the predisenrollment period, compared with 17.2% in the

postdisenrollment period, Dr. Heavrin and his associates reported.

The largest weekly correlation (-0.95) between ED visits among the uninsured and TennCare beneficiaries corresponded exactly to the time when disenrollment began.

When ED use was calculated by calendar year, the incidence of ED visits among the uninsured increased by a relative 34.5%, from 44 visits per 100 persons per year in 2004 to 59.2 visits per 100 persons per year in 2006.

Total ED visits in the state decreased by 74,178 during the study period, which is predictable given a Medicaid population's use of the ED, according to Dr. Heavrin, chief resident, department of emergency medicine, Vanderbilt University Medical Center in Nashville, Tenn. A recent study showed that Medicaid enrollees visited the ED about three times more often than the uninsured (Med. Care 2008;46:1099-107).

An evaluation of admission data by Dr. Heavrin and his associates revealed that the admission rate of uninsured patients increased from 7.5% to 9.3% between the pre-

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disenrollment and postdisenrollment periods, while decreasing slightly from 10.6% to 10.4% among TennCare beneficiaries. Higher admission rates among the uninsured may be related to the acuity of the illness, he explained.

"This is a very worrisome observation that should give states pause before they shed large numbers of people from the rolls of their Medicaid or Medicaid-equivalent program," Dr. Arthur Kellermann, professor of emergency medicine and associate dean for health policy at Emory University in Atlanta, said during a discussion of the study. Dr. Kellermann called for additional analyses into the financial and health consequences of Tennessee's action.

Dr. Donald M. Yealy, professor of emergency medicine, University of Pittsburgh, concurred.

The challenge for emergency physicians is to integrate these outcomes into the broader health policy debate and describe "what really happens downstream and the cost of that, not just in dollars," Dr. Yealy said.

The analysis, based on data from the Healthcare Cost and Utilization Project State Emergency Department database, supports recent findings from a similar study in which ED visits by the uninsured jumped 20% after Oregon disenrolled more than 50,000 Medicaid beneficiaries (Ann. Emerg. Med. 2008 April 15 [doi:10.1016/j.annemergmed.2008.01.335]).

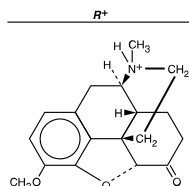
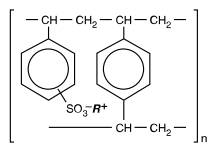
Dr. Heavrin disclosed that the study was supported by a resident research grant from the Emergency Medicine Foundation. ■

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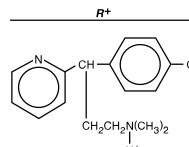
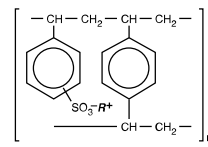
(hydrocodone polistirex and chlorpheniramine polistirex) Extended-Release Suspension

DESCRIPTION: Each teaspoonful (5 mL) of TUSSIONEX Penkinetic Extended-Release Suspension contains hydrocodone polistirex equivalent to 10 mg of hydrocodone bitartrate and chlorpheniramine polistirex equivalent to 8 mg of chlorpheniramine maleate. TUSSIONEX Penkinetic Extended-Release Suspension provides up to 12-hour relief per dose. Hydrocodone is a centrally-acting narcotic antitussive. Chlorpheniramine is an antihistamine. TUSSIONEX Penkinetic Extended-Release Suspension is for oral use only.

Hydrocodone Polistirex: Sulfonated styrene-divinylbenzene copolymer complex with 4,5- α -epoxy-3-methoxy-17-methylmorpholin-6-one.



Chlorpheniramine Polistirex: Sulfonated styrene-divinylbenzene copolymer complex with 2-[p-chloro- α -(2-dimethylamino)ethyl]-benzylpyridine.



Inactive Ingredients: Ascorbic acid, D&C Yellow No. 10, ethylcellulose, FD&C Yellow No. 6, flavin, high fructose corn syrup, methylparaben, polyethylene glycol 3350, polysorbate 80, pregelatinized starch, propylene glycol, propylparaben, purified water, sucrose, vegetable oil, xanthan gum.

CLINICAL PHARMACOLOGY: Hydrocodone is a semisynthetic narcotic antitussive and analgesic with multiple actions qualitatively similar to those of codeine. The precise mechanism of action of hydrocodone and other opiates is not known; however, hydrocodone is believed to act directly on the cough center. In excessive doses, hydrocodone, like other opium derivatives, will depress respiration. The effects of hydrocodone in therapeutic doses on the cardiovascular system are insignificant. Hydrocodone can produce miosis, euphoria, and physical and psychological dependence.

Chlorpheniramine is an antihistamine drug (H₁ receptor antagonist) that also possesses anticholinergic and sedative activity. It prevents released histamine from dilating capillaries and causing edema of the respiratory mucosa.

Hydrocodone release from TUSSIONEX Penkinetic Extended-Release Suspension is controlled by the Penkinetic System, an extended-release drug delivery system, which combines an ion-exchange polymer matrix with a diffusion rate-limiting permeable coating. Chlorpheniramine release is prolonged by use of an ion-exchange polymer system.

Following multiple dosing with TUSSIONEX Penkinetic Extended-Release Suspension, hydrocodone mean (S.D.) peak plasma concentrations of 22.8 (5.9) ng/mL occurred at 3.4 hours. Chlorpheniramine mean (S.D.) peak plasma concentrations of 58.4 (14.7) ng/mL occurred at 6.3 hours following multiple dosing. Peak plasma levels obtained with an immediate-release syrup occurred at approximately 1.5 hours for hydrocodone and 2.8 hours for chlorpheniramine. The plasma half-lives of hydrocodone and chlorpheniramine have been reported to be approximately 4 and 16 hours, respectively.

INDICATIONS AND USAGE: TUSSIONEX Penkinetic Extended-Release Suspension is indicated for relief of cough and upper respiratory symptoms associated with allergy or a cold in adults and children 6 years of age and older.

CONTRAINDICATIONS: TUSSIONEX Penkinetic Extended-Release Suspension is contraindicated in patients with a known allergy or sensitivity to hydrocodone or chlorpheniramine.

The use of TUSSIONEX Penkinetic Extended-Release Suspension is contraindicated in children less than 6 years of age due to the risk of fatal respiratory depression.

WARNINGS: Respiratory Depression: As with all narcotics, TUSSIONEX Penkinetic Extended-Release Suspension produces dose-related respiratory depression by directly acting on brain stem respiratory centers. Hydrocodone affects the center that controls respiratory rhythm and may produce irregular and periodic breathing. Caution should be exercised when TUSSIONEX Penkinetic Extended-Release Suspension is used postoperatively and in patients with pulmonary disease, or whenever ventilatory function is depressed. If respiratory depression occurs, it may be antagonized by the use of naloxone hydrochloride and other supportive measures when indicated (see OVERDOSAGE).

Head Injury and Increased Intracranial Pressure: The respiratory depressant effects of narcotics and their capacity to elevate cerebrospinal fluid pressure may be markedly exaggerated in the presence of head injury, other intracranial lesions, or a pre-existing increase in intracranial pressure. Furthermore, narcotics produce adverse reactions, which may obscure the clinical course of patients with head injuries.

Acute Abdominal Conditions: The administration of narcotics may obscure the diagnosis or clinical course of patients with acute abdominal conditions.

Obstructive Bowel Disease: Chronic use of narcotics may result in obstructive bowel disease especially in patients with underlying intestinal motility disorder.

Pediatric Use: The use of TUSSIONEX Penkinetic Extended-Release Suspension is contraindicated in children less than 6 years of age (see CONTRAINDICATIONS).

In pediatric patients, as well as adults, the respiratory center is sensitive to the depressant action of narcotic cough suppressants in a dose-dependent manner. Caution should be exercised when administering TUSSIONEX Penkinetic Extended-Release Suspension to pediatric patients 6 years of age and older. Overdose or concomitant administration of TUSSIONEX Penkinetic Extended-Release Suspension with other respiratory depressants may increase the risk of respiratory depression in pediatric patients. Benefit to risk ratio should be carefully considered, especially in pediatric patients with respiratory embarrassment (e.g., croup) (see PRECAUTIONS).

PRECAUTIONS: General: Caution is advised when prescribing this drug to patients with narrow-angle glaucoma, asthma, or prostatic hypertrophy.

Special Risk Patients: As with any narcotic agent, TUSSIONEX Penkinetic Extended-Release Suspension should be used with caution in elderly or debilitated patients and those with severe impairment of hepatic or renal function, hypothyroidism, Addison's disease, prostatic hypertrophy, or urethral stricture. The usual precautions should be observed and the possibility of respiratory depression should be kept in mind.

Information for Patients: As with all narcotics, TUSSIONEX Penkinetic Extended-Release Suspension may produce marked drowsiness and impair the mental and/or physical abilities required for the performance of potentially hazardous tasks such as driving a car or operating machinery; patients should be cautioned accordingly. TUSSIONEX Penkinetic Extended-Release Suspension must not be diluted with fluids or mixed with other drugs as this may alter the resin-binding and change the absorption rate, possibly increasing the toxicity.

Patients should be advised to measure TUSSIONEX Penkinetic Extended-Release Suspension with an accurate measuring device. A household teaspoon is not an accurate measuring device and could lead to overdose, especially when a half a teaspoon is measured. A pharmacist can recommend an appropriate measuring device and can provide instructions for measuring the correct dose.

Shake well before using.

Keep out of the reach of children.

Cough Reflex: Hydrocodone suppresses the cough reflex; as with all narcotics, caution should be exercised when TUSSIONEX Penkinetic Extended-Release Suspension is used postoperatively, and in patients with pulmonary disease.

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Drug Interactions: Patients receiving narcotics, antihistaminics, antipsychotics, anti-anxiety agents, or other CNS depressants (including alcohol) concomitantly with TUSSIONEX Penkinetic Extended-Release Suspension may exhibit an additive CNS depression. When combined therapy is contemplated, the dose of one or both agents should be reduced.

The use of MAO inhibitors or tricyclic antidepressants with hydrocodone preparations may increase the effect of either the antidepressant or hydrocodone.

The concurrent use of other anticholinergics with hydrocodone may produce paralytic ileus.

Carcinogenesis, Mutagenesis, Impairment of Fertility: Carcinogenicity, mutagenicity, and reproductive studies have not been conducted with TUSSIONEX Penkinetic Extended-Release Suspension.

Pregnancy: Teratogenic Effects - Pregnancy Category C

Hydrocodone has been shown to be teratogenic in hamsters when given in doses 700 times the human dose. There are no adequate and well-controlled studies in pregnant women. TUSSIONEX Penkinetic Extended-Release Suspension should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Nonteratogenic Effects: Babies born to mothers who have been taking opioids regularly prior to delivery will be physically dependent. The withdrawal signs include irritability and excessive crying, tremors, hyperactive reflexes, increased respiratory rate, increased stools, sneezing, yawning, vomiting, and fever. The intensity of the syndrome does not always correlate with the duration of maternal opioid use or dose.

Labor and Delivery: As with all narcotics, administration of TUSSIONEX Penkinetic Extended-Release Suspension to the mother shortly before delivery may result in some degree of respiratory depression in the newborn, especially if higher doses are used.

Nursing Mothers: It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk and because of the potential for serious adverse reactions in nursing infants from TUSSIONEX Penkinetic Extended-Release Suspension, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

Pediatric Use: The use of TUSSIONEX Penkinetic Extended-Release Suspension is contraindicated in children less than 6 years of age (see CONTRAINDICATIONS and ADVERSE REACTIONS, Respiratory, Thoracic and Mediastinal Disorders).

TUSSIONEX Penkinetic Extended-Release Suspension should be used with caution in pediatric patients 6 years of age and older (see WARNINGS, Pediatric Use).

Geriatric Use: Clinical studies of TUSSIONEX did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. Other reported clinical experience has not identified differences in responses between the elderly and younger patients. In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy.

This drug is known to be substantially excreted by the kidney, and the risk of toxic reactions to this drug may be greater in patients with impaired renal function. Because elderly patients are more likely to have decreased renal function, care should be taken in dose selection, and it may be useful to monitor renal function.

ADVERSE REACTIONS: Gastrointestinal Disorders: Nausea and vomiting may occur; they are more frequent in ambulatory than in recumbent patients. Prolonged administration of TUSSIONEX Penkinetic Extended-Release Suspension may produce constipation.

General Disorders and Administration Site Conditions: Death

Nervous System Disorders: Sedation, drowsiness, mental clouding, lethargy, impairment of mental and physical performance, anxiety, fear, dysphoria, euphoria, dizziness, psychic dependence, mood changes.

Renal and Urinary Disorders: Ureteral spasm, spasm of vesical sphincters, and urinary retention have been reported with opiates.

Respiratory, Thoracic and Mediastinal Disorders: Dryness of the pharynx, occasional tightness of the chest, and respiratory depression (see CONTRAINDICATIONS).

TUSSIONEX Penkinetic Extended-Release Suspension may produce dose-related respiratory depression by acting directly on brain stem respiratory centers (see OVERDOSAGE). Use of TUSSIONEX Penkinetic Extended-Release Suspension in children less than 6 years of age has been associated with fatal respiratory depression. Overdose with TUSSIONEX Penkinetic Extended-Release Suspension in children 6 years of age and older, in adolescents, and in adults has been associated with fatal respiratory depression.

Skin and Subcutaneous Tissue Disorders: Rash, pruritus.

DRUG ABUSE AND DEPENDENCE: TUSSIONEX Penkinetic Extended-Release Suspension is a Schedule III narcotic. Psychic dependence, physical dependence and tolerance may develop upon repeated administration of narcotics; therefore, TUSSIONEX Penkinetic Extended-Release Suspension should be prescribed and administered with caution. However, psychic dependence is unlikely to develop when TUSSIONEX Penkinetic Extended-Release Suspension is used for a short time for the treatment of cough. Physical dependence, the condition in which continued administration of the drug is required to prevent the appearance of a withdrawal syndrome, assumes clinically significant proportions only after several weeks of continued oral narcotic use, although some mild degree of physical dependence may develop after a few days of narcotic therapy.

OVERDOSAGE: Signs and Symptoms: Serious overdose with hydrocodone is characterized by respiratory depression (a decrease in respiratory rate and/or tidal volume, Cheyne-Stokes respiration, cyanosis), extreme somnolence progressing to stupor or coma, skeletal muscle flaccidity, cold and clammy skin, and sometimes bradycardia and hypotension. Although miosis is characteristic of narcotic overdose, mydriasis may occur in terminal narcosis or severe hypoxia. In severe overdosage apnea, circulatory collapse, cardiac arrest and death may occur. The manifestations of chlorpheniramine overdosage may vary from central nervous system depression to stimulation.

Treatment: Primary attention should be given to the reestablishment of adequate respiratory exchange through provision of a patent airway and the institution of assisted or controlled ventilation. The narcotic antagonist naloxone hydrochloride is a specific antidote for respiratory depression which may result from overdosage or unusual sensitivity to narcotics including hydrocodone. Therefore, an appropriate dose of naloxone hydrochloride should be administered, preferably by the intravenous route, simultaneously with efforts at respiratory resuscitation. Since the duration of action of hydrocodone in this formulation may exceed that of the antagonist, the patient should be kept under continued surveillance and repeated doses of the antagonist should be administered as needed to maintain adequate respiration. For further information, see full prescribing information for naloxone hydrochloride. An antagonist should not be administered in the absence of clinically significant respiratory depression. Oxygen, intravenous fluids, vasopressors and other supportive measures should be employed as indicated. Gastric emptying may be useful in removing unabsorbed drug.

DOSE AND ADMINISTRATION: It is important that TUSSIONEX is measured with an accurate measuring device (see PRECAUTIONS, Information for Patients). A household teaspoon is not an accurate measuring device and could lead to overdose, especially when half a teaspoon is to be measured. It is strongly recommended that an accurate measuring device be used. A pharmacist can provide an appropriate measuring device and can provide instructions for measuring the correct dose.

Shake well before using.

Adults and Children 12 Years and Older: 5 mL (1 teaspoonful) every 12 hours; do not exceed 10 mL (2 teaspoonfuls) in 24 hours.

Children 6-11 Years of Age: 2.5 mL (1/2 teaspoonful) every 12 hours; do not exceed 5 mL (1 teaspoonful) in 24 hours. This medicine is contraindicated in children under 6 years of age (see CONTRAINDICATIONS).

HOW SUPPLIED: TUSSIONEX Penkinetic (hydrocodone polistirex and chlorpheniramine polistirex) Extended-Release Suspension is a gold-colored suspension.

NDC 53014-548-67 473 mL bottle

For Medical Information: Contact: Medical Affairs Department / Phone: (866) 822-0068 / Fax: (770) 970-8859

Storage: Shake well. Dispense in a well-closed container.

Store at 20-25°C (68-77°F); excursions permitted to 15-30°C (59-86°F) [see USP Controlled Room Temperature].

TUSSIONEX Penkinetic Extended-Release Suspension

Manufactured for:

UCB, Inc.

Smyrna, GA 30080

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