

# Feds Proffer New Rules for Mental Health Parity

BY JANE ANDERSON

Large group health plans must treat mental health and substance abuse services the same way they treat medical and surgical services under new government regulations that will take effect July 1.

The rules implementing the Mental Health Parity and Addiction Equity Act of 2008 will ensure that plans not impose

a different, more stringent set of restrictions on mental health and substance abuse treatment.

About 150 million Americans receive health insurance coverage through large group health plans, defined in the regulations as those sponsored by employers with 50 or more workers. About 90% of these plans include mental health coverage and therefore will be affected.

The rules, published Feb. 2 in the Fed-

eral Register, will prohibit large group health plans from restricting access to mental health and substance abuse care by limiting benefits and requiring higher patient cost-sharing when compared to general medical or surgical benefits.

The regulations do not require the plans to cover mental health services.

Administration officials speaking on background at a press briefing Jan. 29 said that the rules will bar plans from im-

posing different financial requirements, such as copayments, deductibles, and treatment limits, on mental health and substance abuse benefits.

To fulfill the new rules, financial requirements for mental health and substance abuse services must not be more restrictive than those imposed on "substantially all" medical/surgical benefits.

For example, an administration official said, if a plan expects to pay \$1 million for outpatient, in-network medical services and \$750,000 of that total would be subject to a copayment, that copayment is considered to apply to "substantially all" medical and surgical benefits. The copayment for mental health and substance abuse services could not be any higher, the administration official said.

Plans also will not be allowed to implement separate deductible and out-of-pocket limits for mental health/substance abuse and medical/surgical services; instead, the categories must be combined into a single total deductible or out-of-pocket limit.

The rules also apply to medical management by group health plans. In that case, medical management rules limiting mental health/substance abuse treatment cannot be applied more stringently than are rules limiting medical/surgical treatment unless there are clinically appropriate standards of care that would support the more stringent rules.

Plans must have the same standards for providers to participate in networks for both mental health/substance abuse and medicine/surgery, and must use the same standards for paying usual, customary, and reasonable fees for out-of-network providers, the administration officials said. A plan cannot have in-network providers for medicine/surgery but have only out-of-network providers for mental health/substance abuse. Networks do not have to be comparably sized, the administration officials said.

The regulations were crafted jointly by the departments of Health and Human Services, Labor, and Treasury, administration officials said. Enforcement will occur mainly through state insurance agencies, with backup from the Centers for Medicare and Medicaid Services.

The new rules were published as interim final regulations, allowing for public comment before they take effect.

The Mental Health Parity and Addiction Equity Act of 2008 greatly expanded on an earlier law, the Mental Health Parity Act of 1996. That measure required parity between mental health benefits and medical/surgical benefits only in total lifetime and annual dollar limits.

Most states already have implemented mental health parity laws, although many are far more limited than the new federal law, according to the National Alliance on Mental Illness. Administration officials said there was no evidence that companies and organizations tended to drop their mental health coverage after the implementation of such state laws.

Comments will be accepted through May 3 at [www.regulations.gov](http://www.regulations.gov). ■



## LIDODERM® (Lidocaine Patch 5%)

### Rx only

**Brief Summary** (For full Prescribing Information refer to package insert.)

#### INDICATIONS AND USAGE

LIDODERM is indicated for relief of pain associated with post-herpetic neuralgia. It should be applied only to **intact skin**.

#### CONTRAINDICATIONS

LIDODERM is contraindicated in patients with a known history of sensitivity to local anesthetics of the amide type, or to any other component of the product.

#### WARNINGS

##### Accidental Exposure in Children

Even a used LIDODERM patch contains a large amount of lidocaine (at least 665 mg). The potential exists for a small child or a pet to suffer serious adverse effects from chewing or ingesting a new or used LIDODERM patch, although the risk with this formulation has not been evaluated. It is important for patients to **store and dispose of LIDODERM out of the reach of children, pets, and others.** (See HANDLING AND DISPOSAL)

##### Excessive Dosing

Excessive dosing by applying LIDODERM to larger areas or for longer than the recommended wearing time could result in increased absorption of lidocaine and high blood concentrations, leading to serious adverse effects (see ADVERSE REACTIONS, Systemic Reactions). Lidocaine toxicity could be expected at lidocaine blood concentrations above 5 µg/mL. The blood concentration of lidocaine is determined by the rate of systemic absorption and elimination. Longer duration of application, application of more than the recommended number of patches, smaller patients, or impaired elimination may all contribute to increasing the blood concentration of lidocaine. With recommended dosing of LIDODERM, the average peak blood concentration is about 0.13 µg/mL, but concentrations higher than 0.25 µg/mL have been observed in some individuals.

#### PRECAUTIONS

##### General

**Hepatic Disease:** Patients with severe hepatic disease are at greater risk of developing toxic blood concentrations of lidocaine, because of their inability to metabolize lidocaine normally.

**Allergic Reactions:** Patients allergic to para aminobenzoic acid derivatives (procaine, tetracaine, benzocaine, etc.) have not shown cross sensitivity to lidocaine. However, LIDODERM should be used with caution in patients with a history of drug sensitivities, especially if the etiologic agent is uncertain.

**Non-intact Skin:** Application to broken or inflamed skin, although not tested, may result in higher blood concentrations of lidocaine from increased absorption. LIDODERM is only recommended for use on intact skin.

**Eye Exposure:** The contact of LIDODERM with eyes, although not studied, should be avoided based on the findings of severe eye irritation with the use of similar products in animals. If eye contact occurs, immediately wash out the eye with water or saline and protect the eye until sensation returns.

##### Drug Interactions

**Antiarrhythmic Drugs:** LIDODERM should be used with caution in patients receiving Class I antiarrhythmic drugs (such as tocainide and mexiletine) since the toxic effects are additive and potentially synergistic.

**Local Anesthetics:** When LIDODERM is used concomitantly with other products containing local anesthetic agents, the amount absorbed from all formulations must be considered.

##### Carcinogenesis, Mutagenesis, Impairment of Fertility

**Carcinogenesis:** A minor metabolite, 2, 6-xylydine, has been found to be carcinogenic in rats. The blood concentration of this metabolite is negligible following application of LIDODERM.

**Mutagenesis:** Lidocaine HCl is not mutagenic in Salmonella/mammalian microsome test nor clastogenic in chromosome aberration assay with human lymphocytes and mouse micronucleus test.

**Impairment of Fertility:** The effect of LIDODERM on fertility has not been studied.

##### Pregnancy

**Teratogenic Effects: Pregnancy Category B.** LIDODERM (lidocaine patch 5%) has not been studied in pregnancy. Reproduction studies with lidocaine have been performed in rats at doses up to 30 mg/kg subcutaneously and have revealed no evidence of harm to the fetus due to lidocaine. There are, however, no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, LIDODERM should be used during pregnancy only if clearly needed.

##### Labor and Delivery

LIDODERM has not been studied in labor and delivery. Lidocaine is not contraindicated in labor and delivery. Should LIDODERM be used concomitantly with other products containing lidocaine, total doses contributed by all formulations must be considered.

##### Nursing Mothers

LIDODERM has not been studied in nursing mothers. Lidocaine is excreted in human milk, and the milk: plasma ratio of lidocaine is 0.4. Caution should be exercised when LIDODERM is administered to a nursing woman.

### Rx only

LIDODERM® is a registered trademark of Hind Health Care, Inc.

#### Pediatric Use

Safety and effectiveness in pediatric patients have not been established.

#### ADVERSE REACTIONS

##### Application Site Reactions

During or immediately after treatment with LIDODERM (lidocaine patch 5%), the skin at the site of application may develop blisters, bruising, burning sensation, depigmentation, dermatitis, discoloration, edema, erythema, exfoliation, irritation, papules, petechia, pruritus, vesicles, or may be the locus of abnormal sensation. These reactions are generally mild and transient, resolving spontaneously within a few minutes to hours.

##### Allergic Reactions

Allergic and anaphylactoid reactions associated with lidocaine, although rare, can occur. They are characterized by angioedema, bronchospasm, dermatitis, dyspnea, hypersensitivity, laryngospasm, pruritus, shock, and urticaria. If they occur, they should be managed by conventional means. The detection of sensitivity by skin testing is of doubtful value.

##### Other Adverse Events

Due to the nature and limitation of spontaneous reports in postmarketing surveillance, causality has not been established for additional reported adverse events including:

Asthenia, confusion, disorientation, dizziness, headache, hyperesthesia, hypoesthesia, lightheadedness, metallic taste, nausea, nervousness, pain exacerbated, paresthesia, somnolence, taste alteration, vomiting, visual disturbances such as blurred vision, flushing, tinnitus, and tremor.

##### Systemic (Dose-Related) Reactions

Systemic adverse reactions following appropriate use of LIDODERM are unlikely, due to the small dose absorbed (see CLINICAL PHARMACOLOGY, Pharmacokinetics). Systemic adverse effects of lidocaine are similar in nature to those observed with other amide local anesthetic agents, including CNS excitation and/or depression (light-headedness, nervousness, apprehension, euphoria, confusion, dizziness, drowsiness, tinnitus, blurred or double vision, vomiting, sensations of heat, cold, or numbness, twitching, tremors, convulsions, unconsciousness, respiratory depression, and arrest). Excitatory CNS reactions may be brief or not occur at all, in which case the first manifestation may be drowsiness merging into unconsciousness. Cardiovascular manifestations may include bradycardia, hypotension, and cardiovascular collapse leading to arrest.

#### OVERDOSAGE

Lidocaine overdose from cutaneous absorption is rare, but could occur. If there is any suspicion of lidocaine overdose (see ADVERSE REACTIONS, Systemic Reactions), drug blood concentration should be checked. The management of overdose includes close monitoring, supportive care, and symptomatic treatment. Dialysis is of negligible value in the treatment of acute overdose with lidocaine.

In the absence of massive topical overdose or oral ingestion, evaluation of symptoms of toxicity should include consideration of other etiologies for the clinical effects, or overdosage from other sources of lidocaine or other local anesthetics.

The oral LD<sub>50</sub> of lidocaine HCl is 459 (346-773) mg/kg (as the salt) in non-fasted female rats and 214 (159-324) mg/kg (as the salt) in fasted female rats, which are equivalent to roughly 4000 mg and 2000 mg, respectively, in a 60 to 70 kg man based on the equivalent surface area dosage conversion factors between species.

#### DOSEAGE AND ADMINISTRATION

Apply LIDODERM to intact skin to cover the most painful area. Apply up to three patches, only once for up to 12 hours within a 24-hour period. Patches may be cut into smaller sizes with scissors prior to removal of the release liner. (See HANDLING AND DISPOSAL) Clothing may be worn over the area of application. Smaller areas of treatment are recommended in a debilitated patient, or a patient with impaired elimination.

If irritation or a burning sensation occurs during application, remove the patch (es) and do not reapply until the irritation subsides.

When LIDODERM is used concomitantly with other products containing local anesthetic agents, the amount absorbed from all formulations must be considered.

#### HANDLING AND DISPOSAL

Hands should be washed after the handling of LIDODERM, and eye contact with LIDODERM should be avoided. Do not store patch outside the sealed envelope. Apply immediately after removal from the protective envelope. Fold used patches so that the adhesive side sticks to itself and safely discard used patches or pieces of cut patches where children and pets cannot get to them. LIDODERM should be kept out of the reach of children.

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

Manufactured for:  
**Endo Pharmaceuticals Inc.**  
Chadds Ford, Pennsylvania 19317



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