

# File Claims by Oct. for UnitedHealth Settlement

BY MARY ELLEN SCHNEIDER

If you provided covered out-of-network services to patients insured by UnitedHealth Group between March 1994 and November 2009, you may be eligible to receive payments as part of a \$350 million settlement reached last year.

The American Medical Association estimates that thousands of physicians will be eligible to be paid under the settlement. Notices with instructions for filing claims were mailed in May.

The \$350 million settlement comes after a nearly decade-long legal battle between UnitedHealth Group and several plaintiffs, including the AMA, the Medical Society of the State of New York, and the Missouri State Medical Association. The groups alleged that UnitedHealth Group conspired to systematically underpay physicians for out-of-network medical services by using an industry database of charges to justify lower reimbursements.

Last year, UnitedHealth Group reached a settlement with New York State Attorney General Andrew Cuomo to discontinue use of the database and the company committed \$50 million to fund the development of a new, independent database that will determine the rates paid for out-of-network care.

In a separate settlement, the company agreed to pay \$350 million to reimburse health plan members and out-of-network providers who were underpaid as a result of the flawed database calculations.

Physicians and patients have until July 27, 2010, to opt out of the settlement. Claims for payments from the settlement fund are due by Oct. 5, 2010.

To be eligible to receive part of the settlement, physicians must have provided covered out-of-network services or supplies between March 15, 1994, and Nov. 18, 2009, to patients covered by a health plan that was either administered or insured by UnitedHealthcare, Oxford Health Plans,

Metropolitan Life Insurance Companies, American Airlines, or one of their affiliates. In addition, in order to be eligible, physicians must have been given an assignment by the patient to bill the health plan.

Physicians billed via an assignment if they received a payment directly from the health plan, if they completed box 13 on the HCFA/CMS 1500 form, or if they marked yes in the benefits assignment indicator on an electronic health care claim.

Physicians who are owed money by a patient for a covered out-of-network service or supply cannot file a claim through the settlement; however, they can contact the Settlement Claims Administrator to find out if any of their patients have submitted claims to the settlement fund. ■

For more information, contact the Berdon Claims Administration LLC at 800-443-1073 or [unitedhealthcare@berdonclaimsllc.com](mailto:unitedhealthcare@berdonclaimsllc.com).

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### INTUNIV™ (guanfacine) Extended-Release Tablets

#### Rx Only

**BRIEF SUMMARY:** Consult the Full Prescribing Information for complete product information.

#### INDICATIONS AND USAGE

INTUNIV™ is indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD). The efficacy of INTUNIV™ was studied for the treatment of ADHD in two controlled clinical trials (8 and 9 weeks in duration) in children and adolescents ages 6-17 who met DSM-IV® criteria for ADHD (see *Clinical Studies in Full Prescribing Information*). The effectiveness of INTUNIV™ for longer-term use (more than 9 weeks) has not been systematically evaluated in controlled trials.

**Maintenance Treatment** The effectiveness of INTUNIV™ for longer-term use (more than 9 weeks) has not been systematically evaluated in controlled trials. Therefore the physician electing to use INTUNIV™ for extended periods should periodically re-evaluate the long-term usefulness of the drug for the individual patient.

#### CONTRAINDICATIONS

Patients with a history of hypersensitivity to INTUNIV™, its inactive ingredients (see *Description in Full Prescribing Information*), or other products containing guanfacine (e.g. TENEX®) should not take INTUNIV™.

#### WARNINGS AND PRECAUTIONS

**Hypotension, Bradycardia, and Syncope** Treatment with INTUNIV™ can cause decreases in blood pressure and heart rate. In the pediatric, short-term (8-9 weeks), controlled trials, the maximum mean changes from baseline in systolic blood pressure, diastolic blood pressure, and pulse were -5 mm Hg, -3 mm Hg, and -6 bpm, respectively, for all dose groups combined (generally one week after reaching target doses of 1 mg/day, 2 mg/day, 3 mg/day or 4 mg/day). These changes were dose dependent. Decreases in blood pressure and heart rate were usually modest and asymptomatic; however, hypotension and bradycardia can occur. Hypotension was reported as an adverse event for 6% of the INTUNIV™ group and 4% of the placebo group. Orthostatic hypotension was reported for 1% of the INTUNIV™ group and none in the placebo group. In long-term, open label studies, (mean exposure of approximately 10 months), maximum decreases in systolic and diastolic blood pressure occurred in the first month of therapy. Decreases were less pronounced over time. Syncope occurred in 1% of pediatric subjects in the clinical program. The majority of these cases occurred in the long-term, open-label studies. Measure heart rate and blood pressure prior to initiation of therapy, following dose increases, and periodically while on therapy. Use INTUNIV™ with caution in patients with a history of hypotension, heart block, bradycardia, or cardiovascular disease, because it can decrease blood pressure and heart rate. Use caution in treating patients who have a history of syncope or may have a condition that predisposes them to syncope, such as hypotension, orthostatic hypotension, bradycardia, or dehydration. Use INTUNIV™ with caution in patients treated concomitantly with antihypertensives or other drugs that can reduce blood pressure or heart rate or increase the risk of syncope. Advise patients to avoid becoming dehydrated or overheated.

**Sedation and Somnolence** Somnolence and sedation were commonly reported adverse reactions in clinical studies (38% for INTUNIV™ vs. 12% for placebo) in children and adolescents with ADHD, especially during initial use (see *Adverse Reactions in Full Prescribing Information*). Before using INTUNIV™ with other centrally active depressants (such as phenothiazines, barbiturates, or benzodiazepines), consider the potential for additive sedative effects. Caution patients against operating heavy equipment or driving until they know how they respond to treatment with INTUNIV™. Advise patients to avoid use with alcohol.

**Other Guanfacine-Containing Products** Guanfacine, the active ingredient in INTUNIV™, is also approved as an antihypertensive. Do not use INTUNIV™ in patients concomitantly taking other guanfacine-containing products (e.g., Tenex).

#### ADVERSE REACTIONS

**Clinical Trial Experience** Two short-term, placebo-controlled, double-blind pivotal studies (Studies 1 and 2) were conducted in children and adolescents with ADHD with a dose range of 1 to 4 mg/day of INTUNIV™. The most commonly reported adverse reactions (occurring in ≥2% of patients) that were considered drug-related and reported in a greater percentage of patients taking INTUNIV™ compared to patients taking placebo were: somnolence, headache, fatigue, upper abdominal pain, nausea, lethargy, dizziness, irritability, hypotension/decreased blood pressure, decreased appetite, dry mouth, and constipation. Less common adverse reactions (<2%) reported in pivotal Studies 1 and 2 that occurred in more than one patient taking INTUNIV™ and were more common than in the placebo group are atrioventricular block, bradycardia, sinus arrhythmia, dyspepsia, asthenia, chest pain, increased alanine aminotransferase, increased blood pressure, increased weight, postural dizziness, increased urinary frequency, enuresis, asthma, orthostatic hypotension, and pallor. In addition, the following less common (<2%) psychiatric disorders occurred in more than one patient receiving INTUNIV™ and were more common than in the placebo group. The

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relationship to INTUNIV™ could not be determined because these events may also occur as symptoms in pediatric patients with ADHD: agitation, anxiety, depression, emotional lability, nightmares or interrupted sleep. Twelve percent (12%) of patients receiving INTUNIV™ discontinued from the clinical studies due to adverse events, compared to 4% in the placebo group. The most common adverse reactions leading to discontinuation of INTUNIV™-treated patients from the studies were somnolence/sedation (6%) and fatigue (2%). Less common adverse reactions leading to discontinuation (occurring in approximately 1% of patients) included: hypotension/decreased blood pressure, headache, and dizziness. In the controlled long term studies (mean duration of approximately 10 months) with a dose range of 1 to 4 mg/day of INTUNIV™, the most common adverse reactions (≥5%) reported during open label treatment were somnolence, headache, fatigue, upper abdominal pain, hypotension/decreased blood pressure, vomiting, dizziness, nausea, weight increased, and irritability. The most frequent adverse reactions leading to discontinuation (≥2%) were somnolence (3%), syncopal events (2%), increased weight (2%), depression (2%), and fatigue (2%). Other adverse reactions leading to discontinuation in the long-term studies (occurring in approximately 1% of patients) included: hypotension/decreased blood pressure, sedation, headache, and lethargy. In long-term open label studies, serious adverse reactions occurring in more than one patient were syncope (2%) and convulsion (0.4%). Adverse reactions that occurred in <5% of patients but ≥2% in open-label, long-term studies that are considered possibly related to INTUNIV™ include: syncopal events, constipation, stomach discomfort, hypertension/increased blood pressure, decreased appetite, diarrhea, dry mouth, lethargy, and insomnia.

**Effects on Height, Weight, and Body Mass Index (BMI)** Patients taking INTUNIV™ demonstrated similar growth compared to normative data. Patients taking INTUNIV™ had a mean increase in weight of 1 kg (2 lbs) compared to those receiving placebo over a comparative treatment period. Patients receiving INTUNIV™ for at least 12 months in open-label studies gained an average of 8 kg (17 lbs) in weight and 8 cm (3 in) in height. The height, weight, and BMI percentile remained stable in patients at 12 months in the long-term studies compared to when they began receiving INTUNIV™.

**Laboratory Tests** In short and long-term studies, no clinically important effects were identified on any laboratory parameters.

**Effects on Heart Rate and QT Interval** The effect of two dose levels of immediate-release guanfacine (4 mg and 8 mg) on the QT interval was evaluated in a double-blind, randomized, placebo- and active-controlled, cross-over study in healthy adults. A dose-dependent decrease in heart rate was observed during the first 12 hours, at time of maximal concentrations. The mean change in heart rate was -13 bpm at 4 mg and -22 bpm at 8 mg. An apparent increase in mean QTc was observed for both doses. However, guanfacine does not appear to interfere with cardiac repolarization of the form associated with pro-arrhythmic drugs. This finding has no known clinical relevance.

#### USE IN SPECIFIC POPULATIONS

**Pregnancy: Pregnancy Category B.** There are no adequate and well-controlled studies of guanfacine in pregnant women. This drug should be used during pregnancy only if clearly needed.

**Nursing Mothers:** It is not known whether guanfacine is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when INTUNIV™ is administered to a nursing woman.

**Pediatric Use:** The safety and efficacy of INTUNIV™ in pediatric patients less than 6 years of age have not been established.

**Geriatric Use:** The safety and efficacy of INTUNIV™ in geriatric patients have not been established.

#### DRUG ABUSE AND DEPENDENCE

INTUNIV™ is not a controlled substance and has no known potential for abuse or dependence.

#### OVERDOSAGE

Two cases of accidental overdose of INTUNIV™ were reported in clinical trials in pediatric ADHD patients. These reports included adverse reactions of sedation and bradycardia in one patient and somnolence and dizziness in the other patient. Consult with a Certified Poison Control Center for up to date guidance and advice.

Manufactured for Shire US Inc., Wayne, PA 19087.  
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