

New Health Plans Must Offer Free Screenings

BY MARY ELLEN SCHNEIDER

New health plans will soon be required to offer a range of recommended preventive health services to patients free of charge under the Affordable Care Act.

The requirements will affect new private health plans in the individual and group markets starting with plan years that begin on or after Sept. 23. The

Health and Human Services department estimates that in 2011, the rules will impact about 30 million people in group health plans and another 10 million in individual market plans. The new rules do not apply to grandfathered plans.

The administration released an interim final regulation detailing the new requirements in July.

Under the final rule, health plans may

not collect copayments, coinsurance, or deductibles for a number of recommended preventive services. However, insurers may collect a fee for the associated office visit if the preventive health service was not the primary purpose of the visit.

Patients may also incur cost sharing if they go out of network for the recommended screenings.

The services that are covered include

those given an evidence rating of "A" or "B" from the U.S. Preventive Services Task Force.

Those services include breast and colon cancer screenings, diabetes screenings, blood pressure and cholesterol testing, and screening for vitamin deficiencies during pregnancy. Tobacco cessation counseling is also given a high evidence rating by the U.S. Preventive Services Task Force and would be covered under the new rule.

Health plans will have some extra time to begin covering newly recommended services. For recommendations that have been in effect for less than a year, plans will have 1 year to comply after the effective date, according to the interim final rule.

Health plans will also be required to cover the list of adult and childhood vaccines recommended by the Advisory Committee on Immunization Practices.

Covered services include blood pressure and cholesterol testing, breast and colon cancer screenings, diabetes screenings, and tobacco cessation counseling.

For children, the rule also requires health plans to cover all preventive care recommended under the Bright Futures guidelines.

The guidelines include screenings, developmental assessments, immunizations, and regular well-child visits from birth to the age of 21 years. These guidelines were developed jointly by the Health Resources and Services Administration and the American Academy of Pediatrics.

The rule also calls for coverage of additional preventive services for women, which will be developed by an independent group of experts. The recommendations from that group are expected by Aug. 1, 2011.

There was no word from HHS on whether those recommendations are likely to include coverage for contraceptives, something many reproductive health advocates have been lobbying for in recent months.

HHS officials expect that the move to expand coverage and eliminate out-of-pocket costs for these services will decrease costs for many Americans, especially those at high risk for certain health conditions.

At the same time, the change is expected to increase premiums for those who are enrolled in nongrandfathered plans. The federal government has estimated that premiums in the affected plans could increase by about 1.5% on average. ■

drugs are unlikely because of low extent of metabolism [see *Pharmacokinetics – Valsartan (12.3) in the full prescribing information*].

Transporters: The results from an *in vitro* study with human liver tissue indicate that valsartan is a substrate of the hepatic uptake transporter OATP1B1 and the hepatic efflux transporter MRP2. Coadministration of inhibitors of the uptake transporter (rifampin, cyclosporine) or efflux transporter (ritonavir) may increase the systemic exposure to valsartan.

As with other drugs that block angiotensin II or its effects, concomitant use of potassium sparing diuretics (e.g., spironolactone, triamterene, amiloride), potassium supplements, or salt substitutes containing potassium may lead to increases in serum potassium and in heart failure patients to increases in serum creatinine.

USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Pregnancy Category D [see *Warnings and Precautions (5.1)*].

Valturna contains both aliskiren (a direct renin inhibitor) and valsartan (an angiotensin II receptor blocker). When administered during the second or third trimester of pregnancy, drugs that act directly on the renin-angiotensin-aldosterone system can cause fetal and neonatal morbidity and death. Valturna can cause fetal harm when administered to a pregnant woman. If this drug is used during pregnancy, or if the patient becomes pregnant while taking this drug, apprise the patient of the potential hazard to the fetus.

Angiotensin II receptor antagonists, like valsartan, and angiotensin-converting enzyme (ACE) inhibitors exert similar effects on the renin-angiotensin-aldosterone system. In several dozen published cases, ACE inhibitor use during the second and third trimesters of pregnancy was associated with fetal and neonatal injury, including hypotension, neonatal skull hypoplasia, anuria, reversible or irreversible renal failure, and death. Oligohydramnios was also reported, presumably from decreased fetal renal function. In this setting, oligohydramnios was associated with fetal limb contractures, craniofacial deformation, and hypoplastic lung development. Prematurity, intrauterine growth retardation, and patent ductus arteriosus were also reported, although it is not clear whether these occurrences were due to exposure to the drug. In addition, first trimester use of ACE inhibitors, a specific class of drugs acting on the renin-angiotensin-aldosterone system, has been associated with a potential risk of birth defects in retrospective data.

When pregnancy occurs in a patient using Valturna, discontinue Valturna treatment as soon as possible. Inform the patient about potential risks to the fetus based on the time of gestational exposure to Valturna (first trimester only or later). If exposure occurs beyond the first trimester, perform an ultrasound examination.

In rare cases when another antihypertensive agent cannot be used to treat the pregnant patient, perform serial ultrasound examinations to assess the intraamniotic environment. Routine fetal testing with non-stress tests, biophysical profiles, and/or contraction stress tests may be appropriate based on gestational age and standards of care in the community. If oligohydramnios occurs in these situations, individualized decisions about continuing or discontinuing Valturna treatment and about pregnancy management should be made by the patient, her physician, and experts in the management of high risk pregnancy. Patients and physicians should be aware that oligohydramnios may not appear until after the fetus has sustained irreversible injury.

Closely observe infants with histories of *in utero* exposure to Valturna for hypotension, oliguria, and hyperkalemia. If oliguria occurs, these infants may require blood pressure and renal perfusion support. Exchange transfusion or dialysis may be required to reverse hypotension or support decreased renal function.

No reproductive toxicity studies have been conducted with the combination of aliskiren and valsartan. However, these studies have been conducted for aliskiren as well as valsartan alone [see *Nonclinical Toxicology (13) in the full prescribing information*].

8.3 Nursing Mothers

It is not known whether aliskiren is excreted in human milk, but aliskiren was secreted in the milk of lactating rats. It is not known whether valsartan is excreted in human milk. Valsartan was excreted into the milk of lactating rats; however, animal breast milk drug levels may not accurately reflect human breast milk levels. Because of the potential for adverse effects on the nursing infant, a decision should be made whether to discontinue nursing or discontinue the drug, taking into account the importance of the drug to the mother.

8.4 Pediatric Use

Safety and effectiveness of Valturna in pediatric patients have not been established.

8.5 Geriatric Use

In the short-term controlled clinical trials of Valturna, 99 (15.9%) patients treated with Valturna were ≥ 65 years and 14 (2.2%) were ≥ 75 years.

No overall differences in safety or effectiveness were observed between these subjects and younger subjects, and other reported clinical experience has not identified differences in responses between the elderly and younger patients, but greater sensitivity of some older individuals cannot be ruled out.

10 OVERDOSAGE

Aliskiren

Limited data are available related to overdose in humans. The most likely manifestation of overdose would be hypotension. If symptomatic hypotension occurs, provide supportive treatment.

Valsartan

Limited data are available related to overdose in humans. The most likely effect of overdose with valsartan would be hypotension and tachycardia; bradycardia could occur from parasympathetic (vagal) stimulation. Depressed level of consciousness, circulatory collapse and shock have been reported. If symptomatic hypotension occurs, provide supportive treatment.

Valsartan is not removed from the plasma by hemodialysis.

Valsartan was without grossly observable adverse effects at single oral doses up to 2000 mg/kg in rats and up to 1000 mg/kg in marmosets, except for the salivation and diarrhea in the rat and vomiting in the marmoset at the highest dose (60 and 31 times, respectively, the maximum recommended human dose on a mg/m² basis). (Calculations assume an oral dose of 320 mg/day and a 60-kg patient.)

16 STORAGE

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

Protect from moisture.

Dispense in tight container (USP).

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A list of the recommended preventive services is available online at www.healthcare.gov/center/regulations/prevention/recommendations.html.