

SCHIP Aids Access; Ped Rheum Care Hard to Find

BY MARY ELLEN SCHNEIDER

Nearly 11 million low-income children will receive health coverage under the reauthorization and expansion of the State Children's Health Insurance Program, which was recently signed into law by President Barack Obama.

The legislation (H.R. 2), which received broad support in both the House and Senate, was signed on Feb. 4. The State Children's Health Insurance Program (SCHIP) is now reauthorized through September 2013 and will provide coverage to the approximately 6.7 million children currently covered by the program, as well as 4.1 million new children.

"This bill is only a first step," Mr. Obama said at a signing ceremony for the SCHIP law. "The way I see it, providing coverage to 11 million children through [SCHIP] is a down payment on my commitment to cover every single American. And it is just one component of a much broader effort to finally bring our health care system into the 21st century."

Dr. Thomas J.A. Lehman, chief of the division of pediatric rheumatology at the Hospital for Special Surgery in New York, praised the passage of the SCHIP law, saying that it would benefit many children by helping to improve their access to care.

But the bill falls short for children with rheumatic diseases, he said, because it fails to address the shortage of trained pediatric rheumatologists in the United States.

"Even before the passage of this bill, children with rheumatic disease faced difficulty finding a pediatric rheumatologist to care for them, and long waits for available new-patient appointments if they did find one," he said. "SCHIP may make care more affordable for children with rheumatic disease, but it will not make care more available."

On the same day he signed the SCHIP law, Mr. Obama directed the Centers for Medicare and Medicaid Services to rescind a Bush administration directive that limited the flexibility of states to set higher income eligibility standards for their SCHIP programs.

Under the newly enacted SCHIP law,

states are allowed to cover children in families earning up to 300% of the federal poverty level while retaining access to full federal matching funds. It also gives states the option to cover prenatal care for pregnant women. However, it also requires states to phase out coverage of any low-income parents and childless adults currently covered under the program.

The new law eliminates the 5-year waiting period for legal immigrant children and pregnant women to gain access to SCHIP benefits, a change supported by the American Academy of Pediatrics.

In an effort to measure and improve health care quality, the law calls for development of an initial core set of child health quality measures for children enrolled in SCHIP and Medicaid by Jan. 1, 2010. The measures would be designed to assess the effectiveness and availability of preventive services, prenatal care, and treatments for acute and chronic conditions.

Excluded from the law was a House-passed provision that would have prohibited the construction of new physician-owned specialty hospitals or expansion of existing physician-owned hospitals.

While SCHIP has enjoyed wide support in Congress, members of the House and Senate had a vigorous debate over the last month about whether such a significant expansion of the program was appropriate.

Some Republicans in the House objected to the legislation, saying that it would undermine the original intent of the SCHIP legislation by expanding the program to adults, illegal immigrants, and families with higher incomes.

While the legislation bars the coverage of illegal immigrants, Republicans who spoke out against the legislation said that the lack of an adequate system to verify citizenship status would result in illegal immigrants gaining access to coverage.

The SCHIP law, which will infuse more than \$30 billion into Medicaid over 5 years, will be paid for in large part through a 62-cent-per-pack increase in the federal tax on cigarettes, with proportional increases for other tobacco products. ■

Other Adverse Reactions

Table 10 summarizes events reported in at least 3% of all patients with higher incidence in patients treated with ENBREL compared to controls in placebo-controlled RA trials (including the combination methotrexate trial) and relevant events from Study III. In placebo-controlled plaque psoriasis trials, the percentages of patients reporting injection site reactions were lower in the placebo dose group (6.4%) than in the ENBREL dose groups (15.5%) in Studies I and II. Otherwise, the percentages of patients reporting adverse events in the 50 mg twice a week dose group were similar to those observed in the 25 mg twice a week dose group or placebo group. In psoriasis Study I, there were no serious adverse events of worsening psoriasis following withdrawal of study drug. However, adverse events of worsening psoriasis including three serious adverse events were observed during the course of the clinical trials. Urticaria and non-infectious hepatitis were observed in a small number of patients and angioedema was observed in one patient in clinical studies. Urticaria and angioedema have also been reported in spontaneous post-marketing reports. Adverse events in psoriatic arthritis, ankylosing spondylitis, and plaque psoriasis trials were similar to those reported in RA clinical trials.

Table 10:

Event	Percent of RA Patients Reporting Adverse Events in Controlled Clinical Trials*			
	Placebo Controlled		Active Controlled (Study III)	
	Percent of patients		Percent of patients	
Placebo [†] (N = 152)	ENBREL (N = 349)	MTX (N = 217)	ENBREL (N = 415)	
Injection site reaction	10	37	7	34
Infection (total)**	32	35	72	64
Non-upper respiratory infection (non-URI)**	32	38	60	51
Upper respiratory infection (URI)**	16	29	39	31
Headache	13	17	27	24
Nausea	10	9	29	15
Rhinitis	8	12	14	16
Dizziness	5	7	11	8
Pharyngitis	5	7	9	6
Cough	3	6	6	5
Asthenia	3	5	12	11
Abdominal pain	3	5	10	10
Rash	3	5	23	14
Peripheral edema	3	2	4	8
Respiratory disorder	1	5	NA	NA
Dyspepsia	1	4	10	11
Sinusitis	2	3	3	5
Vomiting	-	3	8	5
Mouth ulcer	1	2	14	6
Alopecia	1	1	12	6
Pneumonitis ("MTX lung")	-	-	2	0

* Includes data from the 6-month study in which patients received concurrent MTX therapy.

[†] The duration of exposure for patients receiving placebo was less than the ENBREL-treated patients.

** Infection (total) includes data from all three placebo-controlled trials. Non-URI and URI include data only from the two placebo-controlled trials where infections were collected separately from adverse events (placebo N = 110, ENBREL N = 213).

In controlled trials of RA and psoriatic arthritis, rates of serious adverse events were seen at a frequency of approximately 5% among ENBREL- and control-treated patients. In controlled trials of plaque psoriasis, rates of serious adverse events were seen at a frequency of < 1.5% among ENBREL- and placebo-treated patients in the first 3 months of treatment. Among patients with RA in placebo-controlled, active-controlled, and open-label trials of ENBREL, malignancies (see **WARNINGS: Malignancies**, **ADVERSE REACTIONS: Malignancies**) and infections (see **ADVERSE REACTIONS: Infections**) were the most common serious adverse events observed. Other infrequent serious adverse events observed in RA, psoriatic arthritis, ankylosing spondylitis, or plaque psoriasis clinical trials are listed by body system below:

Cardiovascular: heart failure, myocardial infarction, myocardial ischemia, hypertension, hypotension, deep vein thrombosis, thrombophlebitis

Digestive: cholecystitis, pancreatitis, gastrointestinal hemorrhage, appendicitis

Hematologic/Lymphatic: lymphadenopathy

Musculoskeletal: bursitis, polymyositis

Nervous: cerebral ischemia, depression, multiple sclerosis (see **WARNINGS: Neurologic Events**)

Respiratory: dyspnea, pulmonary embolism, sarcoidosis

Skin: worsening psoriasis

Urogenital: membranous glomerulonephropathy, kidney calculus

In a randomized controlled trial in which 51 patients with RA received ENBREL 50 mg twice weekly and 25 patients received ENBREL 25 mg twice weekly, the following serious adverse events were observed in the 50 mg twice weekly arm: gastrointestinal bleeding, normal pressure hydrocephalus, seizure, and stroke. No serious adverse events were observed in the 25 mg arm.

Adverse Reactions in Patients with JIA

In general, the adverse events in pediatric patients were similar in frequency and type as those seen in adult patients (see **WARNINGS** and other sections under **ADVERSE REACTIONS**). Differences from adults and other special considerations are discussed in the following paragraphs.

Severe adverse reactions reported in 69 JIA patients ages 4 to 17 years included varicella (see also **PRECAUTIONS: Immunizations**), gastroenteritis, depression/personality disorder, cutaneous ulcer, esophagitis/gastritis, group A streptococcal septic shock, Type 1 diabetes mellitus, and soft tissue and post-operative wound infection.

Forty-three of 69 (62%) children with JIA experienced an infection while receiving ENBREL during three months of study (part 1 open-label), and the frequency and severity of infections was similar in 58 patients completing 12 months of open-label extension therapy. The types of infections reported in JIA patients were generally mild and consistent with those commonly seen in outpatient pediatric populations. Two JIA patients developed varicella infection and signs and symptoms of aseptic meningitis which resolved without sequelae.

The following adverse events were reported more commonly in 69 JIA patients receiving 3 months of ENBREL compared to the 349 adult RA patients in placebo-controlled trials. These included headache (19% of patients, 1.7 events per patient-year), nausea (9%, 1.0 events per patient-year), abdominal pain (19%, 0.74 events per patient-year), and vomiting (13%, 0.74 events per patient-year).

In open-label clinical studies of children with JIA, adverse events reported in those aged 2 to 4 years were similar to adverse events reported in older children.

In post-marketing experience, the following additional serious adverse events have been reported in pediatric patients: abscess with bacteremia, optic neuritis, pancytopenia, seizures, tuberculous arthritis, urinary tract infection (see **WARNINGS**), coagulopathy, cutaneous vasculitis, and transaminase elevations. The frequency of these events and their causal relationship to ENBREL therapy are unknown.

Patients with Heart Failure

Two randomized placebo-controlled studies have been performed in patients with CHF. In one study, patients received either ENBREL 25 mg twice weekly, 25 mg three times weekly, or placebo. In a second study, patients received either ENBREL 25 mg once weekly, 25 mg twice weekly, or placebo. Results of the first study suggested higher mortality in patients treated with ENBREL at either schedule compared to placebo. Results of the second study did not corroborate these observations. Analyses did not identify specific factors associated with increased risk of adverse outcomes in heart failure patients treated with ENBREL (see **PRECAUTIONS: Patients with Heart Failure**).

Adverse Reaction Information from Spontaneous Reports

Adverse events have been reported during post-approval use of ENBREL. Because these events are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to ENBREL exposure.

Additional adverse events are listed by body system below:

Body as a whole: angioedema, fatigue, fever, flu syndrome, generalized pain, weight gain

Cardiovascular: chest pain, vasodilation (flushing), new-onset congestive heart failure (see **PRECAUTIONS: Patients with Heart Failure**)

Digestive: altered sense of taste, anorexia, diarrhea, dry mouth, intestinal perforation

Hematologic/Lymphatic: adenopathy, anemia, aplastic anemia, leukopenia, neutropenia, pancytopenia, thrombocytopenia (see **WARNINGS**)

Hepatobiliary: autoimmune hepatitis

Musculoskeletal: joint pain, lupus-like syndrome with manifestations including rash consistent with subacute or discoid lupus

Nervous: paresthesias, stroke, seizures, and central nervous system events suggestive of multiple sclerosis or isolated demyelinating conditions such as transverse myelitis or optic neuritis (see **WARNINGS**)

Ocular: dry eyes, ocular inflammation

Respiratory: dyspnea, interstitial lung disease, pulmonary disease, worsening of prior lung disorder

Skin: cutaneous vasculitis, erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis, pruritus, subcutaneous nodules, urticaria

Rx Only. This brief summary is based on ENBREL prescribing information v. 35: 12/2008

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