

Mixed Results Seen on Maine's Insurance Mandate

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As more state policy makers consider their options for expanding health insurance coverage, the experience of Maine's Dirigo Health may offer a road map for avoiding potential missteps.

Under the Dirigo Health initiative, which began in 2005, the state offered subsidized health insurance for small businesses, self-employed workers, and low-

and moderate-income individuals through a program called DirigoChoice. In addition, the state increased the annual income eligibility level for its Medicaid program, MaineCare, to include parents of children under age 19 years who were at or below 200% of the federal poverty level.

The goal behind the Dirigo Health initiative has been to provide access to affordable health coverage to every Maine resident by 2009.

While the program has seen success in

targeting subsidies to low-income individuals, it also has run into problems meeting its financial goals and hitting enrollment targets, according to a report commissioned by the Commonwealth Fund. The report evaluated the program as of September 2006.

"The implementation can be just as difficult as actually passing the law," said Debra J. Lipson, lead author of the report and a senior researcher at Mathematica Policy Research Inc., based in Washington, D.C.

When the Dirigo Health Reform Act was passed in 2003, the program was touted as a means to achieve universal access to health insurance and targeted the 136,000 uninsured Maine residents. The state estimated that in the first year of the program, it would enroll about 41,000 individuals.

But the program has fallen short of those expectations and of as of September 2006, had enrolled about 11,100 individuals in DirigoChoice. About 5,000 individuals were enrolled in the MaineCare expansion. An additional 18,100 individuals were covered through an earlier MaineCare expansion that targeted low-income childless adults.

The higher total enrollments in the two MaineCare expansions indicates that states can have success in increasing enrollment when they offer fully subsidized insurance options, the researchers concluded. But, as is in the case in Maine, those expansions come with a large price tag.

Another problem for the Maine program is that DirigoChoice remains unaffordable for many small employers. About 700 small firms were enrolled in the program as of September 2006, comprising about 2.5% of all eligible small businesses. About 83% of firms that did not offer the program or any other health coverage said they failed to offer benefits because premiums were too high, according to the report.

Other states considering similar programs may need to offer stronger incentives to encourage employers to offer coverage and help with employee costs, the researchers wrote.

Paying for the program also has been difficult in Maine. Most of the cost was supposed to be offset by savings from lower uncompensated care. But how savings are measured has been controversial from the start and has not been able to generate enough revenue, according to the Commonwealth Fund report.

The savings offset payment formula even was challenged in court by insurers and the state's chamber of commerce. While the Maine Supreme Court sided with the state in May 2007, the formula is widely viewed as "politically unsustainable in its current form," according to the report.

The type of enrollment in the Dirigo Health program also has created funding problems for Maine. For example, enrollment by previously uninsured individuals has been lower than expected, leading to a lower reduction in charity care costs and limiting the revenues that could be raised for the program. As a result of this and other revenue shortfalls, the state has had to institute periodic enrollment freezes.

Creating affordable health insurance options was a challenge in Maine because there was little provider competition and a highly concentrated insurance market, the report noted. States are likely to be more successful if they have lower health care costs, greater price competition among health plans, or strong regulation that holds down premiums, the researchers concluded. ■

Clindagel®

(clindamycin phosphate gel)
topical gel, 1%

Rx only

Brief Summary

For External Use

INDICATIONS AND USAGE: Clindagel® is indicated for topical application in the treatment of acne vulgaris. In view of the potential for diarrhea, bloody diarrhea and pseudomembranous colitis, the physician should consider whether other agents are more appropriate. (See CONTRAINDICATIONS, WARNINGS, and ADVERSE REACTIONS.)

CONTRAINDICATIONS: Clindagel® is contraindicated in individuals with a history of hypersensitivity to preparations containing clindamycin or lincomycin, a history of regional enteritis or ulcerative colitis, or a history of antibiotic-associated colitis.

WARNINGS: Orally and parenterally administered clindamycin has been associated with severe colitis, which may result in patient death. Use of the topical formulation of clindamycin results in absorption of the antibiotic from the skin surface.

Diarrhea, bloody diarrhea, and colitis (including pseudomembranous colitis) have been reported with the use of topical and systemic clindamycin.

Studies indicate a toxin(s) produced by *Clostridia* is one primary cause of antibiotic-associated colitis. The colitis is usually characterized by severe persistent diarrhea and severe abdominal cramps and may be associated with the passage of blood and mucus. Endoscopic examination may reveal pseudomembranous colitis. Stool culture for *Clostridium difficile* and stool assay for *C. difficile* toxin may be helpful diagnostically.

When significant diarrhea occurs, the drug should be discontinued. Large bowel endoscopy should be considered to establish a definitive diagnosis in cases of severe diarrhea. Antiperistaltic agents, such as opiates and diphenoxylate with atropine, may prolong and/or worsen the condition.

Diarrhea, colitis, and pseudomembranous colitis have been observed to begin up to several weeks following cessation of oral and parenteral therapy with clindamycin.

PRECAUTIONS

General: Clindagel® should be prescribed with caution in atopic individuals.

Drug Interactions: Clindamycin has been shown to have neuromuscular blocking properties that may enhance the action of other neuromuscular blocking agents. Therefore, it should be used with caution in patients receiving such agents.

Carcinogenesis, Mutagenesis, Impairment of Fertility

The carcinogenicity of a 1% clindamycin phosphate gel similar to Clindagel® was evaluated by daily application to mice for two years. The daily doses used in this study were approximately 3 and 15 times higher than the human dose of clindamycin phosphate from 5 milliliters of Clindagel®, assuming complete absorption and based on a body surface area comparison. No significant increase in tumors was noted in the treated animals. A 1% clindamycin phosphate gel similar to Clindagel® caused a statistically significant shortening of the median time to tumor onset in a study in hairless mice in which tumors were induced by exposure to simulated sunlight.

Genotoxicity tests performed included a rat micronucleus test and an Ames Salmonella reversion test. Both tests were negative. Reproduction studies in rats using oral doses of clindamycin hydrochloride and clindamycin palmitate hydrochloride have revealed no evidence of impaired fertility.

Pregnancy: Teratogenic effects—Pregnancy Category B

Reproduction studies have been performed in rats and mice using subcutaneous and oral doses of clindamycin phosphate, clindamycin hydrochloride and clindamycin palmitate hydrochloride. These studies revealed no evidence of fetal harm. The highest dose used in the rat and mouse teratogenicity studies was

equivalent to a clindamycin phosphate dose of 432 mg/kg. For a rat, this dose is 84 fold higher and for a mouse 42 fold higher, than the anticipated human dose of clindamycin phosphate from Clindagel® based on a mg/m² comparison. There are, however, no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed.

Nursing Mothers: It is not known whether clindamycin is excreted in human milk following use of Clindagel®. However, orally and parenterally administered clindamycin has been reported to appear in breast milk. Because of the potential for serious adverse reactions in nursing infants, 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: Safety and effectiveness in children under the age of 12 have not been established.

Geriatric Use: The clinical study with Clindagel® did not include sufficient numbers of patients aged 65 and over to determine if they respond differently than younger patients.

ADVERSE REACTIONS: In the one well-controlled clinical study comparing Clindagel® and its vehicle, the incidence of skin and appendages adverse events occurring in ≥1% of the patients in either group is presented below:

| Body System/Adverse Event | Number (%) of Patients | |
|-------------------------------|------------------------|------------------------|
| | Clindagel® QD N=168 | Vehicle Gel QD N=84 |
| Skin and appendages disorders | | |
| Dermatitis | 0 (0.0) | 1 (1.2) |
| Dermatitis contact | 0 (0.0) | 1 (1.2) |
| Dermatitis fungal | 0 (0.0) | 1 (1.2) |
| Folliculitis | 0 (0.0) | 1 (1.2) |
| Photosensitivity reaction | 0 (0.0) | 1 (1.2) |
| Pruritus | 1 (0.6) | 1 (1.2) |
| Rash erythematous | 0 (0.0) | 0 (0.0) |
| Skin dry | 0 (0.0) | 0 (0.0) |
| Peeling | 1 (0.6) | 0 (0.0) |

Orally and parenterally administered clindamycin has been associated with severe colitis, which may end fatally.

Cases of diarrhea, bloody diarrhea, and colitis (including pseudomembranous colitis) have been reported as adverse reactions in patients treated with oral and parenteral formulations of clindamycin and rarely with topical clindamycin (see WARNINGS). Abdominal pain and gastrointestinal disturbances, as well as gram-negative folliculitis, have also been reported in association with the use of topical formulations of clindamycin.

OVERDOSE: Topically applied Clindagel® may be absorbed in sufficient amounts to produce systemic effects (see WARNINGS).

Reference: 1. Shalita AR, Myers JA, Krochmal L, Yaroshinsky A. The safety and efficacy of clindamycin phosphate foam 1% versus clindamycin phosphate topical gel 1% for the treatment of acne vulgaris. *J Drugs Dermatol.* 2005;4(1):48-56.

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The full report is available online at
www.mathematica-mpr.com/health/dirigochoice.asp.