

# Consumer-Driven Care Still Involves Employers

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WASHINGTON — Although consumer-driven health care puts much more decision making in the hands of consumers, employers and insurers still have a role to play, several speakers said at a meeting on health care competition sponsored by Health Affairs journal and the Center for Studying Health System Change.

Employers will have a role because “as

there’s labor competition for offering health benefits, we have to offer health plans,” said Dr. Robert Galvin, director of corporate health care programs for General Electric. “You’re going to see much more [emphasis] on financial incentives for employees staying healthy and making [good] choices on doctors and hospitals and health plans.”

Another role for employers—although it gets denigrated a bit—is providing access to meaningful, usable, and accurate in-

formation “as long as the market isn’t working on its own, and it certainly isn’t today,” Dr. Galvin said. “This is a responsibility of ours to keep driving at.”

He noted that within GE, officials believe “if information is not readable, it isn’t going to be read.” In light of that philosophy, the company has come up with a “health index” that tells employees things such as how healthy they are, compared with how healthy they want to be; how much money is in their wellness account;

and when it’s time to schedule their children’s physicals. It also can include a scorecard about the providers they use.

This information could be integrated into employee e-mail accounts—a sort of “You’ve Got Health” idea, Dr. Galvin said. “It’s not that this is information you don’t know about, it’s that it’s more usable because it’s part of people’s everyday life.”

Although employers can act as intermediaries, insurers also have a role, said Dr. Samuel Nussbaum, executive vice president and chief medical officer at WellPoint Inc., a multistate Blue Cross and Blue Shield company based in Indianapolis. One of their roles is to make consumers more aware of how much their choices are costing them.

“Most Americans consider health care an entitlement, not a consumer product,” Dr. Nussbaum said. “And consumers are insulated from the true costs of health care services and products. So a prerequisite for health care competition is to have accurate, usable information about cost and quality.”

Insurers also can help steer patients to higher-quality providers, and that means making sure the networks they are in are of high quality, he continued. “It’s not effective enough to have 20% high-quality providers because [consumers] can’t all get to those high-quality providers ... [or] travel around the country for care.”

In addition to helping consumers with purchasing decisions, WellPoint also tries to help consumers decide on treatments by making evidence available on its Web site. “We do this with academic physicians and specialty societies,” Dr. Nussbaum said.

Health plans also can make it beneficial to consumers to get more information, he said. For example, in one of WellPoint’s consumer-driven health plans that uses a health reimbursement account, “we pay consumers more to take health risk assessments, we pay them more to enroll in personal health coaching programs in disease and care management, and we pay them more to graduate.”

And the early results are promising. “You can see the reduction in pharmacy costs of 15% and an increase in preventive care spending; 5% of total medical expenses are going to preventive services rather than only 2% or 3%,” Dr. Nussbaum said.

WellPoint also has a database physicians can consult when they are about to undergo a procedure. “You can go online and learn about a condition and compare hospital quality, so if you are in Los Angeles and require bypass graft surgery, you can find out whether it should be done at UCLA Medical Center or Cedars-Sinai, how many procedures they do, and what their outcomes are.”

To be the consumers’ trusted choice as an intermediary in consumer-driven health care, “we need consistent standards of measurement and transparency in cost and quality,” he concluded. “As we do this and adopt consumer-friendly tools with the right benefit design, and work with delivery systems to be organized around centers of excellence, ... we can drive true change in our health care system.”

**BRIEF SUMMARY**

Revised: January 2006

**Protopic®**  
(tacrolimus)

Ointment 0.03%

Ointment 0.1%

**FOR DERMATOLOGIC USE ONLY  
NOT FOR OPHTHALMIC USE**

**Rx Only**

See boxed **WARNING** concerning long-term safety of topical calcineurin inhibitors

**INDICATIONS AND USAGE**

PROTOPIC Ointment, both 0.03% and 0.1% for adults, and only 0.03% for children aged 2 to 15 years, is indicated as *second-line therapy* for the short-term and non-continuous chronic treatment of moderate to severe atopic dermatitis in non-immunocompromised adults and children who have failed to respond adequately to other topical prescription treatments for atopic dermatitis, or when those treatments are not advisable.

PROTOPIC Ointment is not indicated for children younger than 2 years of age (see boxed **WARNING, WARNINGS** and **PRECAUTIONS: Pediatric Use**).

**CONTRAINDICATIONS**

PROTOPIC (tacrolimus) Ointment is contraindicated in patients with a history of hypersensitivity to tacrolimus or any other component of the ointment.

**WARNINGS**

**WARNING**

**Long-term Safety of Topical Calcineurin Inhibitors Has Not Been Established**

Although a causal relationship has not been established, rare cases of malignancy (e.g., skin and lymphoma) have been reported in patients treated with topical calcineurin inhibitors, including PROTOPIC Ointment.

Therefore:

- Continuous long-term use of topical calcineurin inhibitors, including PROTOPIC Ointment, in any age group should be avoided, and application limited to areas of involvement with atopic dermatitis.
- PROTOPIC Ointment is not indicated for use in children less than 2 years of age. Only 0.03% PROTOPIC Ointment is indicated for use in children 2-15 years of age.

Prolonged systemic use of calcineurin inhibitors for sustained immunosuppression in animal studies and transplant patients following systemic administration has been associated with an increased risk of infections, lymphomas, and skin malignancies. These risks are associated with the intensity and duration of immunosuppression.

Based on the information above and the mechanism of action, there is a concern about potential risk with the use of topical calcineurin inhibitors, including PROTOPIC Ointment. While a causal relationship has not been established, rare cases of skin malignancy and lymphoma have been reported in patients treated with topical calcineurin inhibitors, including PROTOPIC Ointment.

Therefore:

- PROTOPIC Ointment should not be used in immunocompromised adults and children.
- If signs and symptoms of atopic dermatitis do not improve within 6 weeks, patients should be re-examined by their healthcare provider and their diagnosis be confirmed (see **PRECAUTIONS: General**).
- The safety of PROTOPIC Ointment has not been established beyond one year of non-continuous use.

(See boxed **WARNING, INDICATIONS AND USAGE, and DOSAGE AND ADMINISTRATION**).

**PRECAUTIONS**

**General**

The use of PROTOPIC Ointment should be avoided on pre-malignant and malignant skin conditions. Some malignant skin conditions, such as cutaneous T-cell lymphoma (CTCL), may mimic atopic dermatitis.

The use of PROTOPIC Ointment in patients with Netherton’s Syndrome or other skin diseases where there is the potential for increased systemic absorption of tacrolimus is not recommended. The safety of PROTOPIC Ointment has not been established in patients with generalized erythroderma.

The use of PROTOPIC Ointment may cause local symptoms such as skin burning (burning sensation, stinging, soreness) or pruritus. Localized symptoms are most common during the first few days of PROTOPIC Ointment application and typically improve as the lesions of atopic dermatitis resolve. With PROTOPIC Ointment 0.1%, 90% of the skin burning events had a duration between 2 minutes and 3 hours (median 15 minutes). 90% of the pruritus events had a duration between 3 minutes and 10 hours (median 20 minutes). (See **ADVERSE REACTIONS**).

**Bacterial and Viral Skin Infections**

Before commencing treatment with PROTOPIC Ointment, cutaneous bacterial or viral infections at treatment sites should be resolved. Studies have not evaluated the safety and efficacy of PROTOPIC Ointment in the treatment of clinically infected atopic dermatitis.

While patients with atopic dermatitis are predisposed to superficial skin infections including eczema herpeticum (Kaposi’s varicelliform eruption), treatment with PROTOPIC Ointment may be independently associated with an increased risk of varicella zoster virus infection (chicken pox or shingles), herpes simplex virus infection, or eczema herpeticum.

**Patients with Lymphadenopathy**

In clinical studies, 112/13494 (0.8%) cases of lymphadenopathy were reported and were usually related to infections (particularly of the skin) and noted to resolve upon appropriate antibiotic therapy. Of these 112 cases, the majority had either a clear etiology or were known to resolve. Transplant patients receiving immunosuppressive regimens (e.g., systemic tacrolimus) are at

increased risk for developing lymphoma; therefore, patients who receive PROTOPIC Ointment and who develop lymphadenopathy should have the etiology of their lymphadenopathy investigated. In the absence of a clear etiology for the lymphadenopathy, or in the presence of acute infectious mononucleosis, PROTOPIC Ointment should be discontinued. Patients who develop lymphadenopathy should be monitored to ensure that the lymphadenopathy resolves.

**Sun Exposure**

During the course of treatment, patients should minimize or avoid natural or artificial sunlight exposure, even while PROTOPIC is not on the skin. It is not known whether PROTOPIC Ointment interferes with skin response to ultraviolet damage.

**Immunocompromised Patients**

The safety and efficacy of PROTOPIC Ointment in immunocompromised patients have not been studied.

**Renal Insufficiency**

Rare post-marketing cases of acute renal failure have been reported in patients treated with PROTOPIC Ointment. Systemic absorption is more likely to occur in patients with epidermal barrier defects especially when PROTOPIC is applied to large body surface areas. Caution should also be exercised in patients predisposed to renal impairment.

**Information for Patients**

(See Medication Guide)

Patients using PROTOPIC Ointment should receive and understand the information in the Medication Guide. Please refer to the Medication Guide for providing instruction and information to the patient.

**What is the most important information patients should know about PROTOPIC Ointment?**

The safety of using PROTOPIC Ointment for a long period of time is not known. A very small number of people who have used PROTOPIC Ointment had had cancer (for example, skin or lymphoma). However, a link with PROTOPIC Ointment has not been shown. Because of this concern, instruct patients:

- Do not use PROTOPIC Ointment continuously for a long time.
- Use PROTOPIC Ointment only on areas of skin that have eczema.
- Do not use PROTOPIC Ointment on a child under 2 years old.

**PROTOPIC Ointment comes in two strengths:**

- Only PROTOPIC Ointment 0.03% is for use on children aged 2 to 15 years.
- Either PROTOPIC Ointment 0.03% or 0.1% can be used by adults and children 16 years and older.

Advise patients to talk to their prescriber for more information.

**How should PROTOPIC Ointment be used?**

Advise patients to:

- Use PROTOPIC Ointment exactly as prescribed.
- Use PROTOPIC Ointment only on areas of skin that have eczema.
- Use PROTOPIC Ointment for short periods, and if needed, treatment may be repeated with breaks in between.
- Stop PROTOPIC Ointment when the signs and symptoms of eczema, such as itching, rash, and redness go away, or as directed.
- Follow their doctor’s advice if symptoms of eczema return after treatment with PROTOPIC Ointment.
- Call their doctor if:
  - Their symptoms get worse with PROTOPIC Ointment.
  - They get an infection on their skin.
  - Their symptoms do not improve after 6 weeks of treatment. Sometimes other skin diseases can look like eczema.

**To apply PROTOPIC Ointment:**

Advise patients:

- Wash their hands before applying PROTOPIC.
- Apply a thin layer of PROTOPIC Ointment twice daily to the areas of skin affected by eczema.
- Use the smallest amount of PROTOPIC Ointment needed to control the signs and symptoms of eczema.
- If they are a caregiver applying PROTOPIC Ointment to a patient, or if they are a patient who is not treating their hands, wash their hands with soap and water after applying PROTOPIC. This should remove any ointment left on the hands.
- Do not bathe, shower, or swim right after applying PROTOPIC. This could wash off the ointment.
- Moisturizers can be used with PROTOPIC Ointment. Make sure they check with their doctor first about the products that are right for them. Because the skin of patients with eczema can be very dry, it is important to keep up good skin care practices. If they use moisturizers, apply them after PROTOPIC Ointment.

**What should patients avoid while using PROTOPIC Ointment?**

Advise patients:

- Do not use ultraviolet light therapy, sun lamps, or tanning beds during treatment with PROTOPIC Ointment.
- Limit sun exposure during treatment with PROTOPIC Ointment even when the medicine is not on their skin. If patients need to be outdoors after applying PROTOPIC Ointment, wear loose fitting clothing that protects the treated area from the sun. Doctors should advise what other types of protection from the sun patients should use.
- Do not cover the skin being treated with bandages, dressings or wraps. Patients can wear normal clothing.
- Avoid getting PROTOPIC Ointment in the eyes or mouth. Do not swallow PROTOPIC Ointment. Patients should call their doctor if they swallow PROTOPIC Ointment.

**Drug Interactions**

Formal topical drug interaction studies with PROTOPIC Ointment have not been conducted. Based on its extent of absorption, interactions of PROTOPIC Ointment with systemically administered drugs are unlikely to occur but cannot be ruled out. The concomitant administration of known CYP3A4 inhibitors in patients with widespread and/or erythrodermic disease should be done with caution. Some examples of such drugs are erythromycin, itraconazole, ketoconazole, fluconazole, calcium channel blockers and cimetidine.

**Carcinogenesis, Mutagenesis, Impairment of Fertility**

No evidence of genotoxicity was seen in bacterial (*Salmonella* and *Escherichia coli*) or mammalian (Chinese hamster lung-derived cells) *in vitro* CHO/HGPRT assay of mutagenicity, the *in vitro* CHO/HGPRT assay of mutagenicity, or *in vivo* clastogenicity assays performed in mice. Tacrolimus did not cause unscheduled DNA synthesis in rodent hepatocytes.

Reproductive toxicology studies were not performed with topical tacrolimus.

**Pregnancy**

**Teratogenic Effects: Pregnancy Category C**

There are no adequate and well-controlled studies of topically administered tacrolimus in pregnant women. The experience with PROTOPIC Ointment when used by pregnant women is too limited to permit assessment of the safety of its use during pregnancy. There are no adequate and well-controlled studies of systemically administered tacrolimus in pregnant women. Tacrolimus is transferred across the placenta. The use of systemically administered tacrolimus during pregnancy has been associated with neonatal hyperkalemia and renal dysfunction. PROTOPIC Ointment should be used during pregnancy only if the potential benefit to the mother justifies a potential risk to the fetus.

**Nursing Mothers**

Although systemic absorption of tacrolimus following topical applications of PROTOPIC Ointment is minimal relative to systemic administration, it is known that tacrolimus is excreted in human milk. Because of the potential for serious adverse reactions in nursing infants from tacrolimus, 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**

PROTOPIC Ointment is not indicated for children less than 2 years of age.

Only the lower concentration, 0.03%, of PROTOPIC Ointment is recommended for use as a *second-line therapy* for short-term and non-continuous chronic treatment of moderate to severe atopic dermatitis in non-immunocompromised children 2 to 15 years of age who have failed to respond adequately to other topical prescription treatments for atopic dermatitis, or when those treatments are not advisable.

The long-term safety and effects of PROTOPIC Ointment on the developing immune system are unknown (see boxed **WARNING, WARNINGS** and **INDICATIONS AND USAGE**).

The most common adverse events associated with PROTOPIC Ointment application in pediatric patients were skin burning and pruritus (see **ADVERSE REACTIONS**). In addition to skin burning and pruritus, the less common events (< 5%) of varicella zoster (mostly chicken pox), and vesiculobullous rash were more frequent in patients treated with PROTOPIC Ointment 0.03% compared to vehicle. In the open-label safety studies, the incidence of adverse events, including infections, did not increase with increased duration of study drug exposure or amount of ointment used. In about 4,400 pediatric patients treated with PROTOPIC Ointment, 24 (0.5%) were reported with eczema herpeticum. Since the safety and efficacy of PROTOPIC Ointment have not been established in pediatric patients below 2 years of age, its use in this age group is not recommended.

**Geriatric Use**

Four hundred and four (404) patients ≥ 65 years old received PROTOPIC Ointment in phase 3 studies. The adverse event profile for these patients was consistent with that for other adult patients.

**ADVERSE REACTIONS**

No photoallergy or no photoallergenicity were detected in clinical studies with 12 and 216 normal volunteers, respectively. One out of 198 normal volunteers showed evidence of sensitization in a contact sensitization study.

The following table depicts the adjusted incidence of adverse events pooled across the 3 identically designed 12-week controlled studies for patients in vehicle, PROTOPIC Ointment 0.03%, and PROTOPIC Ointment 0.1% treatment groups. The table also depicts the unadjusted incidence of adverse events in four safety studies, regardless of relationship to study drug.

**Incidence of Treatment Emergent Adverse Events**

	12-Week, Randomized, Double-Blind, Phase 3 Studies		Open-Label Studies (up to 3 years)		Total
	Vehicle (n=212)	PROTOPIC Ointment (n=216)	Vehicle (n=402)	PROTOPIC Ointment (n=404)	
Skin Burning†	26	46	58	29	43
Pruritus	19	23	31	25	28
Flu-like symptoms†	19	23	31	25	28
Allergic Reaction	8	12	5	8	4
Skin Erythema	20	25	28	13	12
Headache	11	20	19	8	5
Skin Infection	11	12	5	14	10
Fever	4	4	1	13	21
Infection	1	1	2	9	7
Cough Increased	2	1	1	14	18
Asthma	4	6	4	6	4
Herpes Simplex	4	4	4	2	4
Eczema Herpeticum	0	1	1	0	2
Pharyngitis	3	3	4	11	6
Accidental Injury	4	3	6	3	6
Postular Rash	2	3	4	3	2
Folliculitis	1	6	4	0	4
Rhinitis	4	3	2	2	6
Otitis Media	4	0	1	6	12
Sinusitis	1	4	2	3	6
Diarrhea	3	3	4	2	4
Urticaria	3	3	6	1	3
Lack of Drug Effect	1	1	0	1	1
Bronchitis	0	2	2	3	4
Vomiting	0	1	1	7	6
Maculopapular Rash	2	2	2	3	0
Rash†	1	1	2	2	3
Abdominal Pain	3	1	1	2	3
Fungal Dermatitis	0	2	1	3	0
Gastroenteritis	1	2	2	3	0
Alcohol Intolerance†	0	3	1	0	4
Acne†	2	4	7	1	0
Sunburn	1	2	1	0	0
Skin Disorder	2	2	1	4	2
Contact Dermatitis	0	2	2	2	3
Pain	1	2	1	0	1
Vesiculobullous Rash†	3	3	2	0	4
Lymphadenopathy	2	2	1	0	3
Nausea	4	3	2	0	4
Skin Tingling†	2	3	8	1	2
Face Eczema	2	2	1	2	1
Dyspepsia	1	1	4	0	2

Dry Skin	7	3	3	0	1	1	1	1
Hypoaesthesia	1	3	7	0	0	2	0	1
Skin Necrosis	1	1	1	0	0	1	2	2
Back Pain†	0	2	2	1	1	3	0	2
Peripheral Edema	2	4	3	0	0	2	0	1
Varicella Zoster/Herpes Zoster ‡	0	1	0	0	5	1	2	2
Contact Dermatitis	1	3	3	3	4	2	2	2
Asthma	1	2	3	0	0	1	0	1
Pneumonia	0	1	1	2	0	1	3	2
Eczema	2	2	2	0	0	1	0	1
Insomnia	3	4	3	1	1	2	0	1
Exfoliative Dermatitis	3	3	1	0	0	0	1	0
Dysmenorrhea	2	4	4	0	0	2	1	1
Prostrial Abscess	1	0	1	0	0	1	0	1
Cyst†	0	3	2	0	0	2	1	1
Cellulitis	0	1	3	0	0	1	0	1
Exacerbation of Untreated Area	1	0	1	1	0	1	1	1
Procedural Complication	1	0	0	1	0	1	1	1
Hypertension	0	0	1	0	0	2	0	1
Tooth Disorder	0	1	1	1	0	2	1	1
Atrial fibrillation	1	1	3	2	0	2	1	2
Depression	1	2	1	0	0	1	0	1
Paresthesia	1	3	3	0	0	2	1	2
Ataxia	0	1	1	0	0	1	1	1
Urinary Tract Infection	0	0	1	0	0	2		