

Compliance Alert

February 1, 2006

Compliance Alert, provided by Group Benefit Services, gives you the most up to date information regarding industry news as well as legislation and regulatory activities affecting your health plan.

TOPIC: EMERGING THERAPEUTIC ISSUE FROM ESI

On January 20, 2006, the U.S. Food and Drug Administration (FDA) announced approval of the updated labeling for two topical drugs to treat eczema, Elidel® Cream (pimecrolimus - Novartis) and Protopic® Ointment (tacrolimus - Astellas). The changes will now include a BOXED WARNING about the possible risk of cancer and a medication guide will be distributed to ensure that patients using these medications are aware of this concern. Although a causal link has not been established, rare reports of cancer (e.g. skin and lymphoma) have been reported in patients who had been receiving these products. The labeling change includes the following:

- The new labeling clarifies that these drugs are recommended for use as second-line treatments for the short-term and non-continuous chronic treatment of mild to moderate atopic dermatitis in non-immunocompromised adults and children two years of age and older.
- Use of these drugs in children under two years of age is not recommended.
- A Medication Guide providing information about the risks of therapy will be distributed by the pharmacist with each prescription or refill of the medication.

Express Scripts response:

- Physicians who have prescribed Elidel or Protopic within the past 120 days will receive a communication summarizing the information provided by FDA. The physician communication will also contain a patient profile to help them identify impacted patients.
- The above communication will only be distributed for those clients enrolled in the physician mailing portion of the Emerging Therapeutic Issues Program.

If you have any questions regarding this information, please contact your Group Benefit Services Account Manager at 1.800.638.6085.

This communication is not intended to be legal advice and should not be construed as legal advice. If you have any legal questions or concerns about your plan, GBS recommends seeking counsel from an ERISA attorney.

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