

Annual Review – Fiscal Year 2008
Immunomodulators: Elidel[®]/Protopic[®]
Oklahoma Health Care Authority
January 2009

Current Product Based Prior Authorization Criteria

With respect to the immunomodulator topical medications there are two products in this therapeutic category. Both are immunosuppressants classified as topical calcineurin inhibitors.

- The first 90 days of a 12 month period will be covered without a prior authorization if member meets age requirement.
- After the initial period, authorization will be granted with documentation of one trial of a topical corticosteroid for six weeks duration within the past 90 days.
- Therapy will be approved only once each 90 day period to ensure appropriate short-term and intermittent utilization as advised by the FDA.
- Quantities will be limited to 30 grams for use on the face, neck, and groin, and 100 grams for all other areas.
- Authorizations will be restricted to those patients who are not immunocompromised.

FDA Approved Indications:

- **Elidel[®]** (Pimecrolimus) for short-term and intermittent treatment of mild to moderate *atopic dermatitis (eczema)*
- **Protopic[®]** (Tacrolimus) for short-term and intermittent treatment of moderate to severe *atopic dermatitis (eczema)*

Age Restriction:

- **Elidel[®] 1% Cream** ≥ 2 years of age
- **Protopic[®] 0.03% Cream** ≥ 2 years of age
- **Protopic[®] 0.1% Cream** ≥ 15 years of age

Clinical exceptions for topical corticosteroid trials for members meeting age requirement:

- Documented adverse effect, drug interaction, or contraindication to topical corticosteroid products
- Atopic dermatitis on the face, neck, or groin where physician does not want to use topical corticosteroids
- Prescription by allergist or dermatologist (*regardless of age*)

Utilization in Oklahoma SoonerCare Population

During the period between July 2007 and June 2008 a total of 3,135 members had claims for topical immunosuppressant drugs paid through SoonerCare.

FY 2008 versus FY 2007			% Change
Cost FY '08		\$ 711,638.67	11.4 ↓
	<i>Cost FY '07</i>	\$ 803,196.84	
Claims FY '08		5,239	20.0 ↓
	<i>Claims FY '07</i>	6,512	
Per Diem FY '08		\$ 4.60	5.0 ↑
	<i>Per Diem FY '07</i>	\$ 4.39	
Members FY '08		3,135	22.0 ↓
	<i>Members FY '07</i>	4,024	

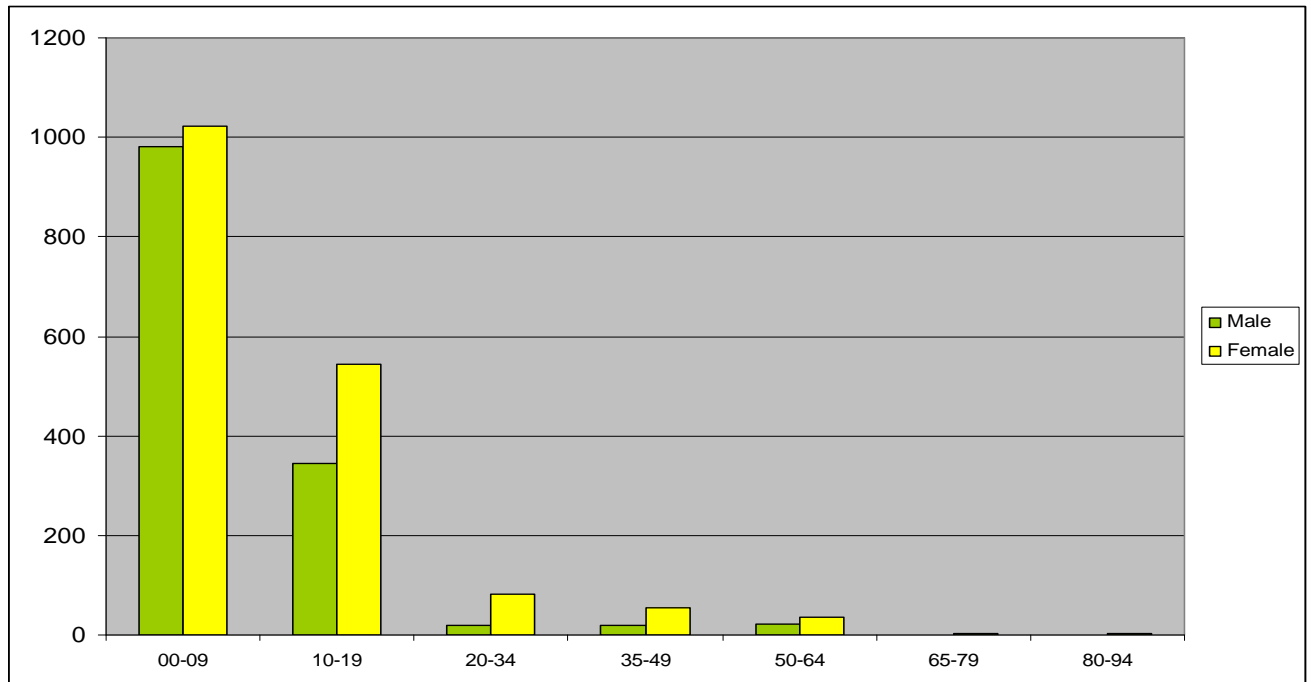
Utilization FY '08

Drugname	Total Claims	Total Units**	Total Days	Members	Total Paid
Elidel Cream 1%	4,403	246,583	129,944	2,721	\$570,480.90
Protopic Ointment 0.03%	714	42,700	20,702	403	\$119,500.00
Protopic Ointment 0.1%	122	7,810	3,987	78	\$21,657.77
TOTAL	5,239	297,093	154,633	3,135*	\$711,638.67

*Unduplicated members FY '08.

**Average quantity per day for intermittent use is 1.6 grams/day; SoonerCare average in FY '06 = 3.6 grams/day and in FY '08 = 2.0 grams/day. (Novartis safety update February 2005)

Age and Gender FY '08



Petition Summary FY '08

Total Petitions: 856

Approved.....	268
Denied.....	398
Incomplete.....	175

Recommendations

The College of Pharmacy does not recommend any changes at this time and will continue to monitor and evaluate this PBPA category according to current treatment guidelines and FDA approved product labeling.