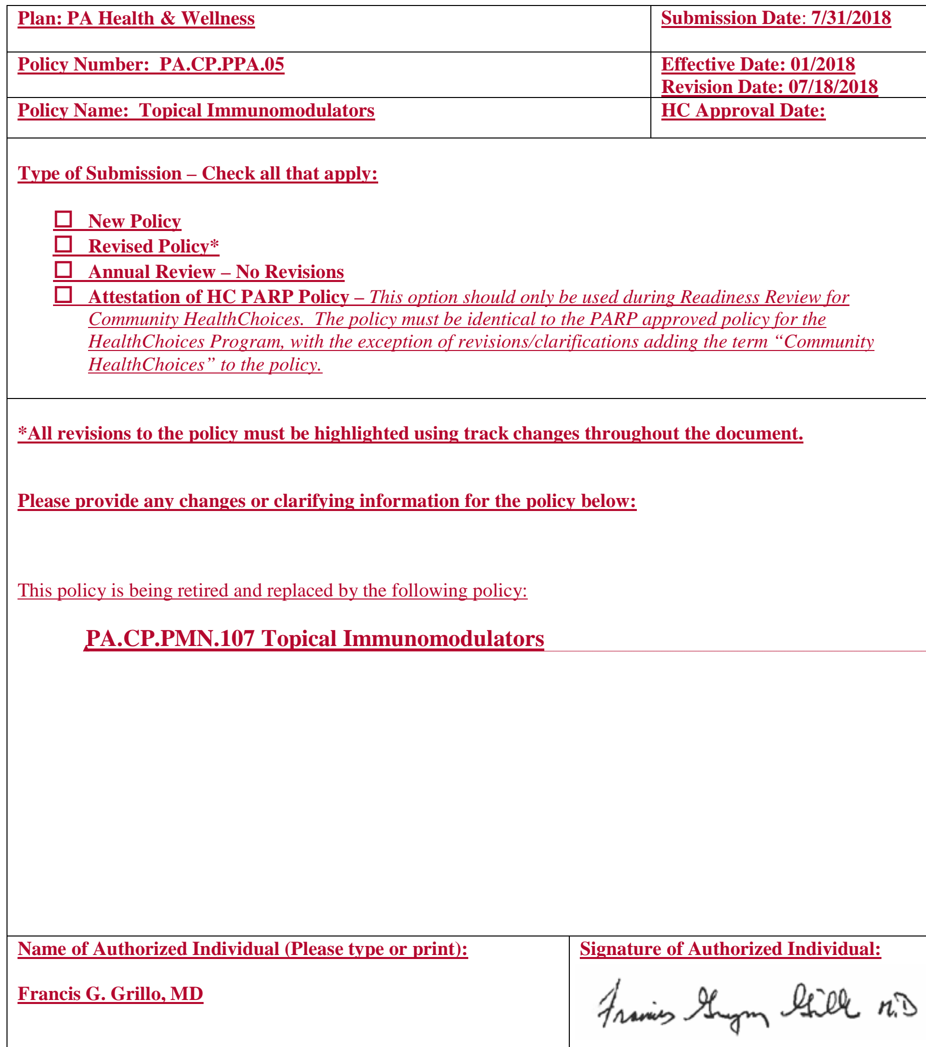
Prior Authorization Review Panel

CHC-MCO Policy Submission

A separate copy of this form must accompany each policy submitted for review.
Policies submitted without this form will not be considered for review.



Plan: PA Health & Wellness	**Submission Date: 7/31/2018**
Policy Number: PA.CP.PPA.05	**Effective Date: 01/2018** **Revision Date: 07/18/2018**
Policy Name: Topical Immunomodulators	**HC Approval Date:**

Type of Submission – Check all that apply:

- ☐ **New Policy**
- ☐ **Revised Policy***
- ☐ **Annual Review – No Revisions**
- ☐ **Attestation of HC PARP Policy –** *This option should only be used during Readiness Review for Community HealthChoices. The policy must be identical to the PARP approved policy for the HealthChoices Program, with the exception of revisions/clarifications adding the term "Community HealthChoices" to the policy.*

***All revisions to the policy must be highlighted using track changes throughout the document.**

Please provide any changes or clarifying information for the policy below:

This policy is being retired and replaced by the following policy:

PA.CP.PMN.107 Topical Immunomodulators

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Name of Authorized Individual (Please type or print):	**Signature of Authorized Individual:**
Francis G. Grillo, MD	Francis Gregory Grillo M.D

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Clinical Policy: Topical Immunomodulators

Reference Number: PA.CP.PPA.05
Effective Date: 01/18
Last Review Date: 11/17
Line of Business: Medicaid

Coding Implications
Revision Log

Description
Pimecrolimus (Elidel®) and tacrolimus (Protopic®) are topical immunomodulators requiring prior authorization.

FDA approved indication
Elidel cream is indicated for

- Second-line therapy for the short-term and non-continuous chronic treatment of mild to moderate atopic dermatitis in non-immunocompromised adults and children 2 years of age and older, who have failed to respond adequately to other topical prescription treatments, or when those treatments are not advisable

Protopic ointment is indicated for

- 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

Policy/Criteria
** Provider must submit documentation (including office chart notes and lab results) supporting that member has met all approval criteria **

It is the policy of Pennsylvania Health and Wellness® that topical immunomodulators are **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Atopic Dermatitis (must meet all)**:**
1. Diagnosis of atopic dermatitis;
2. Member is immunocompetent;
3. Member must meet one of the following (a, b, or c):
   a. Children and adolescents: Failure of 2 medium potency corticosteroids in the previous 6 months, unless member has contraindication(s) to all PDL topical corticosteroids;
   b. Adults: Failure of 2 high or very high potency corticosteroids in the previous 6 months, unless member has contraindication(s) to all PDL topical corticosteroids;
   c. Use on the face or skinfolds;
4. If request is for tacrolimus 0.03% ointment, member is ≥ 2 years of age;
5. If request is for tacrolimus 0.1% ointment, member is ≥ 16 years of age;
6. Request does not exceed 30 gm tube per month.

Approval duration: 3 months

B. Vitiligo: Approve for 3 months
C. Other diagnoses/indications – Refer to PA.CP.PMN.53 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized)

II. Continued Therapy

A. Atopic Dermatitis (must meet all)**:**
1. Currently receiving medication via Pennsylvania Health and Wellness benefit or member has previously met initial approval criteria or Continuity of Care policy applies;
2. Responding positively to therapy;
3. Request does not exceed 30 gm tube per month.

Approval duration: 6 months

B. Other diagnoses/indications (must meet 1 or 2)**:**
1. Currently receiving medication via Pennsylvania Health and Wellness benefit and documentation supports positive response to therapy; or
2. Refer to PA.CP.PMN.53 if requested indication is NOT listed under section III (Diagnoses/Indications for which coverage is NOT authorized)

Approval duration: 3 months

III. Diagnoses/Indications for which coverage is NOT authorized:
~~A. Vitiligo~~
B. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policy – PA.CP.PMN.53 or evidence of coverage documents

IV. Appendices/General Information

Appendix A: Abbreviation Key
PDL: preferred drug list

V. Dosage and Administration

Drug	**Recommended Dose**
Elidel (pimecrolimus)	A thin layer to affected skin twice daily
Protopic (tacrolimus)	A thin layer to affected skin twice daily

VI. Product Availability

Drug	**Availability**
Elidel (pimecrolimus)	1% cream
Protopic (tacrolimus)	0.03% ointment, 0.1% ointment

VII. References

1. Elidel Package Insert. Bridgewater, NJ: Valeant Pharmaceuticals North America LLC., August 2014. Available at http://valeant.com. Accessed November 2016.

2. Protopic Package Insert. Northbrook, IL: Astellas Pharma US, Inc., May 2012. Available at https://dailymed.nlm.nih.gov/. Accessed November 2016.
3. Eichenfield LF, Tom WL, Berger TG et al. Guidelines of care for the management of atopic dermatitis: Section 2. Management and treatment of atopic dermatitis with topical therapies. J Am Acad Dermatol. 2014 Aug;71(1):116-32.

Reviews, Revisions, and Approvals	Date	Approval Date
This policy is being retired and replaced by the following policy: **PA.CP.PMN.107 Topical Immunomodulators**	7/18	