Clinical Policy Title: Psoriasis dermatology treatment

Clinical Policy Number: 16.02.06

Effective Date: October 1, 2017
Initial Review Date: September 17, 2016
Most Recent Review Date: September 21, 2017
Next Review Date: August, 2018

Related policies:

CP # 16.02.08  Vitiligo dermatology treatment

ABOUT THIS POLICY: AmeriHealth Caritas Pennsylvania has developed clinical policies to assist with making coverage determinations. AmeriHealth Caritas Pennsylvania’s clinical policies are based on guidelines from established industry sources, such as the Centers for Medicare & Medicaid Services (CMS), state regulatory agencies, the American Medical Association (AMA), medical specialty professional societies, and peer-reviewed professional literature. These clinical policies along with other sources, such as plan benefits and state and federal laws and regulatory requirements, including any state- or plan-specific definition of “medically necessary,” and the specific facts of the particular situation are considered by AmeriHealth Caritas Pennsylvania when making coverage determinations. In the event of conflict between this clinical policy and plan benefits and/or state or federal laws and/or regulatory requirements, the plan benefits and/or state and federal laws and/or regulatory requirements shall control. AmeriHealth Caritas Pennsylvania’s clinical policies are for informational purposes only and not intended as medical advice or to direct treatment. Physicians and other health care providers are solely responsible for the treatment decisions for their patients. AmeriHealth Caritas Pennsylvania’s clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, AmeriHealth Caritas Pennsylvania will update its clinical policies as necessary. AmeriHealth Caritas Pennsylvania’s clinical policies are not guarantees of payment.

Coverage policy

AmeriHealth Caritas Pennsylvania considers psoriasis to be a remediable medical condition and the use of treatments specified in this policy to be clinically proven and, therefore, medically necessary when the following criteria are met (Shreberk-Hassidim 2017, Mehraban 2014, Di Meglio 2014, Leonardi 2008, Leonardi 2003):

- Diagnosis is made of psoriasis by a primary care or specialty physician knowledgable in the diagnosis (i.e., clinical evaluation, skin biopsy) and treatment of the condition.

- Treatment administered is an established method of care for psoriasis:
  - Anthralin.
  - Corticosteroids (e.g., betamethasone dipropionate ointment and fluocinonide cream).
  - Keratolytic agents (e.g., lactic acid, salicylic acid, and urea).
  - Retinoids (e.g., tazarotene).
  - Tar preparations.
  - Vitamin D derivatives (e.g., calcipotriene).
  - Biologic therapies as outlined by PerformRx in “Specialty Biologic Agents for Psoriasis”
Limitations:

All other treatments for psoriasis are considered to be investigational and, therefore, not medically necessary.

Alternative covered services

Primary care and specialty physician (including surgical) evaluation and management.

Background

Psoriasis is a common, chronic, disfiguring inflammatory and proliferative disorder of the skin.

Topical and oral corticosteroids are among several therapeutic agents that have efficacy in treatment of psoriasis. Very potent topical steroids are widely used to treat the disorder but the evidence for their effectiveness is limited. Folliculitis is a common side effect of treatment with potent topical steroids. Long-term daily treatment with oral corticosteroids, in most patients, requires continued treatment to maintain response and benefit is usually insufficient to justify the risks.

Anthralin (Dithranol®, Drithocreme®) is an adjunctive therapy but only a small proportion of patients seem to achieve cosmetically worthwhile results. Dithranol needs to be applied sufficiently frequently and in a high enough concentration to produce a brisk irritant reaction in order to be effective. Staining of hair limits its use in fair-haired individuals. Impressive therapeutic responses have also been seen in those with psoriasis treated with alefacept. In common with other immune-mediated complex diseases, there is no definitive cure for psoriasis, and available treatment is only to decrease disease activity and improve symptoms.

Searches

AmeriHealth Caritas Pennsylvania searched PubMed and the databases of:

- UK National Health Services Centre for Reviews and Dissemination.
- Agency for Healthcare Research and Quality’s National Guideline Clearinghouse and other evidence-based practice centers.
- The Centers for Medicare & Medicaid Services (CMS).

We conducted searches on August 7, 2017. Search terms were “vitiligo and psoriasis,” “vitiligo” and “psoriasis.” We included:

- **Systematic reviews**, which pool results from multiple studies to achieve larger sample sizes and greater precision of effect estimation than in smaller primary studies. Systematic reviews use
predetermined transparent methods to minimize bias, effectively treating the review as a scientific endeavor, and are thus rated highest in evidence-grading hierarchies.

- Guidelines based on systematic reviews.
- Economic analyses, such as cost-effectiveness, and benefit or utility studies (but not simple cost studies), reporting both costs and outcomes — sometimes referred to as efficiency studies — which also rank near the top of evidence hierarchies.

Findings

Mehraban (2014) conducted a systematic review of the 308nm xenon-chloride excimer laser in treatment of dermatologic disorders and reported verified efficacy in treating skin conditions such as vitiligo, psoriasis, atopic dermatitis, alopecia areata, allergic rhinitis, folliculitis, granuloma annulare, lichen planus, mycosis fungoides, palmoplantar pustulosis, pityriasis alba, CD30+ lympho proliferative disorder, leukoderma, prurigo nodularis, and localized scleroderma and genital lichen sclerosus.

A narrative review (DiMeglio, 2014) identified classic therapies of psoriasis that span from topical treatments (emollients, topical corticosteroids, vitamin D analogs) used in mild-to-moderate psoriasis, to UVA/UVB phototherapy or systemic therapies reserved to moderate-to-severe cases. Among systemic therapies, which include retinoids, methotrexate, and cyclosporine, the folic acid antagonist methotrexate, which has immunosuppressive, cytostatic, and anti-inflammatory activity and is rather inexpensive, is often used as first line of treatment. However, classic therapy has not completely met patients’ needs, especially in the most severe cases. In the past decade, a better understanding of disease immunopathogenesis has been successfully translated into new drugs, known as “biologics,” targeting key inflammatory mediators and currently representing an effective third-line therapy in moderate-to-severe psoriasis patients, unresponsive to nonbiologic systemic agents.

Leonardi (2003) demonstrated that tumor necrosis factor (TNF) blockade, using etanercept, is an effective therapeutic strategy for psoriasis. Etanercept is a human p75 TNF receptor fusion protein, similar in therapeutic concept to infliximab, a humanized chimeric anti-TNF monoclonal antibody, or adalimumab, a fully human monoclonal antibody. Etanercept efficacy has been shown in three phase III trials with about 50 percent of patients achieving good responses at week 12 of therapy. TNF neutralization causes early down-modulation of myeloid cell-related genes, with decrease of Th17 cell products and downstream molecules in just 2 weeks after commencing therapy. Interestingly, only patients who downregulate the expression of Th17 pathway genes successfully respond to etanercept treatment.

The latest biologic to be approved for psoriasis, ustekinumab, is a monoclonal antibody simultaneously blocking the heterodimeric proteins IL-12 and IL- 23 via its biding to the shared subunit p40. Its efficacy is quite high, with 67 percent of patients achieving response at 12 weeks of treatment (Leonardi 2008). Shreberk-Hassidim (2017) conducted a systematic review of the literature (18 clinical trials) to determine the efficacy and safety of janus kinase (JAK) inhibitors as a treatment modality for many inflammatory conditions, among them psoriasis, showing beneficial results that were comparable to the
effects achieved by etanercept. Promising preliminary results were also reported for vitiligo, dermatitis, graft versus host disease, cutaneous T cell lymphoma, and lupus erythematosus. The most common adverse events reported were infections, mostly nasopharyngitis and upper respiratory tract infections.

Summary of clinical evidence:

<table>
<thead>
<tr>
<th>Citation</th>
<th>Content, Methods, Recommendations</th>
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</thead>
<tbody>
<tr>
<td>Shreberk-Hassidim (2017)</td>
<td>Key points:</td>
</tr>
</tbody>
</table>
| Janus kinase inhibitors in dermatology: A systematic review | - A systematic review (18 clinical trials) evaluated JAK inhibitors for psoriasis.  
- Promising preliminary results were also reported for vitiligo, dermatitis, graft versus host disease, cutaneous T cell lymphoma, and lupus erythematosus.  
- The most common adverse events reported were infections, mostly nasopharyngitis and upper respiratory tract infections. |
| Mehraban (2014)                   | Key points:                       |
| The 308nm excimer laser in dermatology. | - Systematic review on 308-nm excimer laser in dermatological disorders.  
- Showed efficacy in treating vitiligo, psoriasis, atopic dermatitis, alopecia areata, allergic rhinitis, folliculitis, granuloma annulare, lichen planus, mycosis fungoides, palmoplantar pustulosis, pityriasis alba, CD30+ lympho proliferative disorder, leukoderma, prurigo nodularis, localized scleroderma and genital lichen sclerosus. |
| Di Meglio (2014)                  | Key points:                       |
| Psoriasis                         | - Narrative review of lassic therapies of psoriasis identified topical treatments (emollients, topical corticosteroids, vitamin D analogs) used in mild-to-moderate psoriasis, to UVA/UVB phototherapy or systemic therapies reserved to moderate-to-severe cases.  
- Among systemic therapies, which include retinoids, methotrexate, and cyclosporine, the folic acid antagonist methotrexate, which has immunosuppressive, cytostatic, and anti-inflammatory activity is often used as first line of treatment.  
- Targeting key inflammatory mediators currently represents an effective third-line therapy in moderate-to-severe psoriasis patients, unresponsive to nonbiologic systemic agents. |
| Leonardi (2008)                   | Key points:                       |
| PHOENIX 1 study investigators.    | - Multicenter study of TNF blockade, using etanercept, a human p75 TNF receptor fusion protein.  
- Etanercept achieved response in 50% of patients at week 12. |
| Leonardi (2003)                   | Key points:                       |
| Etanercept as monotherapy in patients with psoriasis | - Clinical trial report suggested TNF blockade is an effective therapeutic strategy for psoriasis.  
- Three phase III trials with about 50% of patients achieved good responses at week 12 of therapy. |

References

Professional society guidelines/others:

Peer-reviewed references:


Hubiche T, Leaute-Labreze C, Taieb A et al. Poor long-term outcome of severe vitiligo and psoriasis in


**CMS National Coverage Determinations (NCDs):**


**Local Coverage Determinations (LCDs):**


**Commonly submitted codes**

Below are the most commonly submitted codes for the service(s)/item(s) subject to this policy. This is not an exhaustive list of codes. Providers are expected to consult the appropriate coding manuals and bill accordingly.

<table>
<thead>
<tr>
<th>CPT Code</th>
<th>Description</th>
<th>Comment</th>
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<tbody>
<tr>
<td>96999</td>
<td>Unlisted special dermatological service or procedure [excimer laser]</td>
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<tr>
<td>96910</td>
<td>Photochemotherapy; tar and ultraviolet B (Goeckerman treatment) or petrolatum and ultraviolet B</td>
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</tr>
<tr>
<td>96912</td>
<td>Photochemotherapy: psoralens and ultraviolet A (PUVA)</td>
<td></td>
</tr>
<tr>
<td>96913</td>
<td>Photochemotherapy (Goeckerman and/or PUVA) for severe photoresponsive dermatoses requiring at least four to eight hours of care under direct supervision of the physician (includes application of medication and dressings)</td>
<td></td>
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<tr>
<td>96920</td>
<td>Laser treatment for inflammatory skin disease (psoriasis); total area less than 250 sq cm</td>
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<tr>
<td>96921</td>
<td>Laser treatment for inflammatory skin disease (psoriasis); 250 sq cm to 500 sq cm</td>
<td></td>
</tr>
<tr>
<td>96922</td>
<td>Laser treatment for inflammatory skin disease (psoriasis); over 500 sq cm</td>
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<table>
<thead>
<tr>
<th>ICD-10 Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>L40.0-L40.9</td>
<td>Psoriasis</td>
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<tr>
<td>L80</td>
<td>Vitiligo</td>
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<thead>
<tr>
<th>HCPCS Code Level II</th>
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<tbody>
<tr>
<td>J7507</td>
<td>Tacrolimus, immediate release, oral 1 mg</td>
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</tr>
<tr>
<td>J7508</td>
<td>Tacrolimus, extended release, oral 0.1 mg</td>
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PERFORMRx PRIOR AUTHORIZATION CRITERIA for Specialty Biological Agents for Psoriasis

PREFERRED STATUS: Preferred Biological Agents- Require Prior Authorization
ENBREL® (etanercept)
HUMIRA® (adalimumab)
INFLECTRA (infliximab-dyyb)

PREFERRED STATUS: Non-Preferred Biological Agents- Require Prior Authorization (Second Line)
REMICADE® (infliximab)
OTEZLA® (Apemilast)
COSENTYS® (Secukinumab)
STELARA® (ustekinumab) TALTZ (ixekizumab)
Or any newly marketed agent

PA CRITERIA FOR APPROVAL FOR PSORIASIS:
• The member is an adult (>18 yo) and has a documented clinical diagnosis of moderate to severe plaque psoriasis.
• Documentation that the patient has had (consistent with pharmacy claims data, OR for new members to the health plan consistent with medical chart history) adequate trials (including dates and doses) of at least 3 of the treatment bullet points listed below:
  o The use of topical steroids or has a documented medical reason for not using this therapy to manage their medical condition.
  o The use of a topical medication [i.e. Dovonex® (calcipotriene), Tazorac® (tazarotene), salicylates, or a topical tar preparation] that is indicated for the treatment of psoriasis or has a documented medical reason for not using any of these therapies to manage their medical condition.
  o The use of methotrexate or has a documented medical reason (e.g. history of liver or kidney disease, pregnancy, severe cytopenia, alcoholism) for not using this therapy to manage their medical condition.
  o The use of cyclosporine or has a documented medical reason for not using this therapy to manage their medical condition.
  o The use of oral methotrexate or has a documented medical reason for not using this therapy to manage their medical condition.
  o The use of U/V/B phototherapy or PUVA (psoralen – oral or topical methoxsalen plus UVA therapy) or has a documented medical reason (e.g. pregnancy, skin cancer, hypersensitivity due to pre-existing disease state – e.g. systemic lupus erythematosus, cataracts) for not undergoing U/V/B phototherapy or PUVA to manage their medical condition.
• Documentation was submitted indicating that the member was evaluated for active or latent TB infection (i.e. tuberculin skin test) as indicated in the package insert.
• The medication requested has an FDA approved indication for use in patients with moderate to severe plaque psoriasis and is being recommended or prescribed by a dermatologist at an FDA-approved dosage.
• If the request is for a non-preferred agent, documented (consistent with pharmacy claims data, OR for new members to the health plan consistent with medical chart history) adequate trial of the preferred biological agents.

If all of the above conditions are met, the request will be approved for up to a 6 month duration. If all of the above criteria are not met, the request is referred to a Medical Director/clinical reviewer for medical necessity review.

PA CRITERIA FOR RE-AUTHORIZATION FOR PSORIASIS:
• The medication is being recommended and prescribed by a dermatologist at an FDA-approved dosage.
• The member has been receiving the medication and documentation was provided that the prescriber has evaluated the member and recommends continuation of therapy.
• Documentation submitted indicates that the member has obtained clinical benefit from the medication.

If all of the above conditions are met, the request will be approved for a 6-month duration for Remicade requests and for a 12 month duration for requests for all other medications. If all of the above criteria are not met, the request is referred to a Medical Director/clinical reviewer for medical necessity review.

NOTE: Medical Director/clinical reviewer must override criteria when, in his/her professional judgment, the requested item is medically necessary.
Revision/Review Date: 11/2016