Clinical Policy Title: Intralesional steroid injection for acne

Clinical Policy Number: 16.02.07

Effective Date: June 1, 2017
Initial Review Date: April 19, 2017
Most Recent Review Date: May 19, 2017
Next Review Date: May 2018

Related policies:
CP# 16.02.04 Phototherapy and photochemotherapy (PUVA) for skin conditions
CP# 16.02.03 Alopecia areata
CP# 16.03.08 Cosmetic, plastic, and scar revision surgery
CP# 17.02.04 Hidradenitis suppurativa

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 the use of intralesional injection with triamcinolone acetonide to be clinically proven and, therefore, medically necessary treatment for the following indications:

- Individual, inflammatory nodulocystic acne lesions.
- Hidradenitis suppurativa/acne inversa (HS) Hurley stage I or II.

Limitations:

Intralesional steroid injections for all other types of acne lesions are not medically necessary.

Intralesional steroid injection to smooth or reduce visible acne scarring is a cosmetic procedure and not medically necessary.

Routine intralesional steroid injections are not medically necessary for members with multiple lesions. Contraindications to intralesional steroid injections with triamcinolone acetonide include (Zaenglein, 2016):

- Site of active infections, such as impetigo or herpes.
- Previous hypersensitivity to triamcinolone.
- Active tuberculosis or systemic fungal infection when using large injections.
- Extensive plaque psoriasis, pustular psoriasis, or erythrodermic psoriasis.
- Active peptic ulcer disease.
- Uncontrolled diabetes, heart failure, or severe hypertension.
- Severe depression or psychosis.

**Alternative covered services:**

- Topical therapies (e.g., retinoids, benzoyl peroxide, antibiotics, azelaic acid, dapsone, salicylic acid, and combinations).
- Oral antibiotics.
- Isotretinoin.
- Hormonal agents.
- Surgery.
- Laboratory monitoring for serum lipids, liver function, and hematologic function (baseline, after one month, and after three months).
- Pregnancy test monthly, if applicable.

**Background**

Acne vulgaris (or “acne”) is a chronic, androgen-dependent, inflammatory dermatosis affecting the pilosebaceous follicles of the skin. The current understanding of acne pathogenesis is continuously evolving, and both adolescents and adults can be affected. Acne is associated with a significant financial burden and considerable psychological distress (Nast, 2012).

Acne presents with a spectrum of signs. It most commonly affects the face, and to a lesser extent, the back and chest. Scarring usually follows deep-seated inflammatory lesions, but may also occur as a result of more superficial inflamed lesions in scar-prone patients. There is no uniform agreement on the best methods for assessing acne (Nast, 2012). More than 25 different methods have been described, but most have not been validated. Objective assessment typically consists of evaluating: dominant lesions; the presence or absence of inflammation, which is particularly difficult to capture; the extent of involvement; and the presence of, or potential for, scarring. The acne types may encompass (Nast, 2012):

- Comedonal acne – clinically non-inflamed lesions that encompass both open (blackheads) and closed comedones (whiteheads).
- Papulopustular acne – a mixture of non-inflammatory and inflammatory lesions and may be superficial or deep. This type of acne can range from mild to severe forms.
- Nodular or conglobate acne – a rare but severe form of acne found most commonly in adult males, on the trunk, upper limbs, and buttocks. Its characteristics include multiple grouped comedones amid inflammatory papules, tender, suppurative nodules, which commonly coalesce to form sinus tracts, and extensive and disfiguring scarring.
Other rare variants – may be severe and associated with genetic or iatrogenic endocrinopathies. These include: acne fulminans; gram-negative folliculitis; rosacea fulminans; and chloracne.

HS is a pathological follicular disease characterized by painful, recurrent nodules and abscesses that rupture and lead to the formation of sinus tracts and scarring (Scheinfeld, 2013). These lesions primarily affect the axilla, waist, groin, perianal, perineal, and inframammary areas. The goals of HS treatment are palliative, and rarely curative, to heal existing lesions, reduce the extent and progression of the disease, and bring the disease activity to the mildest stage possible.

For HS, the Hidradenitis Suppurativa Clinical Response (HiSCR) system is a valid clinical endpoint that takes into account the inflammatory component of HS, but the Hurley Staging System is the most common method used to describe the degree of inflammation and fibrosis of HS (Scheinfeld, 2013; Hurley, 1996):

- **Stage I** — abscess formation (single or multiple) without sinus tracts and scarring.
- **Stage II** — recurrent abscesses with sinus tracts and scarring, single or multiple widely separated lesions.
- **Stage III** — diffuse or almost diffuse involvement or multiple interconnected sinus tracts and abscesses across the entire area.

Treatment options for acne vulgaris consist of over-the-counter medications, prescription medications, and in-office procedures. Prescription medications may be topical, systemic antibiotics, and hormonal therapy. Physical modalities such as pulsed dye laser, glycolic acid peels, and salicylic acid peels, and intralesional corticosteroid injections are other options. Several factors, such as the patient’s age, site of involvement, extent and severity of disease, scarring, quality of life, and patient preference will influence choice of treatment. Each option varies in the quality of the evidence supporting its effectiveness (Nast, 2012).

**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 March 13, 2017. Search terms were: “Triamcinolone,” “Injections, Intralesional” (MeSH), “Steroids” (MeSH), “Hidradenitis Suppurativa” (MeSH), and “Acne Vulgaris/therapy” (MeSH), and the free text terms “acne vulgaris” and “intralesional injection.”

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**

We identified two individual studies and one evidence-based guideline for this policy. The American Academy of Dermatology (AAD) considers intralesional steroid injection using triamcinolone acetonide established treatment for the occasional or particularly stubborn inflamed nodulocystic lesion, but not for patients with multiple lesions (Zaenglein, 2016). These findings are based on extensive clinical experience with this treatment and the results of two low quality studies by Mahajan (2003) and Levine (1983) that suggested significant short-term improvement of individual nodulocystic lesions in appearance and discomfort.

Evidence-based guidance for HS recommends intralesional corticosteroids as a second-line treatment for HS, based on their ability to control pain and reduce inflammation in mild-to-moderate (Hurley stage I or II) lesions (Gulliver, 2016). While local atrophy, systemic absorption of steroids, and possible adrenal suppression may occur, decreasing the concentration and the volume of steroid used will usually minimize these complications (Gulliver, 2016; Zaenglein, 2016).

**Policy updates:**

None.

**Summary of clinical evidence:**

<table>
<thead>
<tr>
<th>Citation</th>
<th>Content, Methods, Recommendations</th>
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<tbody>
<tr>
<td>Gulliver (2016)</td>
<td><strong>Key points:</strong></td>
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</table>
| Guideline: HS based on European guidelines |   • First-line treatments recommended: topical clindamycin twice daily for mild to moderate HS; systemic clindamycin plus rifampicine and tetracycline; and surgery for scarring and Hurley stage III lesions. Analgesics and corticosteroids may be considered to control pain and reduce inflammation.  
   • Weak recommendation issued for intralesional corticosteroids as a second-line treatment for HS based on low quality (level IV) evidence. |
| Zaenglein (2016) for the AAD    | **Key points:**                                                         |
| Guideline: acne vulgaris        |   • Intralesional steroid injection with triamcinolone acetonide is indicated for larger, individual, inflammatory nodulocystic acne and acne keloidalis (based on consensus, opinion, case studies, or disease-oriented evidence).  
   • Intralesional steroid injections demonstrate rapid improvement and decreased pain. Local atrophy, systemic absorption of steroids, and possible adrenal suppression may occur, but decreasing the concentration and the volume of steroid used will minimize these complications. |
| Ingram (2015)                   | **Key points:**                                                         |
Citation | Content, Methods, Recommendations
--- | ---
Cochrane review Interventions for HS | • Systematic review of 12 RCTs (615 total patients).  
• Overall quality: low. Most were small studies, and one RCT supported most interventions.  
• Highest quality evidence supports biologics.  
• No RCT evidence supports several commonly used treatments, including intralesional triamcinolone acetate injections.
Mahajan (2003) (abstract only) Intralesional steroid injection with or without intralesional antibiotics for acne | **Key points:**  
• A small study compared the effectiveness of intralesional triamcinolone acetonide (2.5 mg/ml) in 10 patients to intralesional triamcinolone acetonide plus lincomycin hydrochloride (75 mg/ml) in nine patients. Follow up was at 48 hours, one week and one month later.  
• At one week, seven (70%) patients treated with injection triamcinolone showed 66% improvement versus nine (100%) patients treated with lincomycin and triamcinolone showed 100% improvement, which was stable at one month.
Levine (1983) (abstract only) Intralesional corticosteroids for nodulocystic acne | **Key points:**  
• Triamcinolone acetonide at a concentration of 0.63 mg/mL was as efficacious as a higher concentration of 2.5 mg/mL.  
• Betamethasone phosphate had little, if any, effect on nodulocystic acne lesions at concentrations of 3.0, 1.5, and 0.75 mg/mL, when compared with saline controls.

References

**Professional society guidelines/other:**


**Peer-reviewed references:**


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

No NCDs identified as of the writing of this policy.

**Local Coverage Determinations (LCDs):**

No LCDs identified as of the writing of this policy.

**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.

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