Clinical Policy Title: Surgery for hidradenitis suppurativa

Clinical Policy Number: 17.02.04

Effective Date: July 1, 2016
Initial Review Date: April 27, 2016
Most Recent Review Date: April 19, 2017
Next Review Date: April 2018

Related policies:
None.

ABOUT THIS POLICY: AmeriHealth Caritas has developed clinical policies to assist with making coverage determinations. AmeriHealth Caritas’ 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 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’ 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’ clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, AmeriHealth Caritas will update its clinical policies as necessary. AmeriHealth Caritas’ clinical policies are not guarantees of payment.

Coverage policy

AmeriHealth Caritas considers the use of surgery for hidradenitis suppurativa (HS) to be clinically proven and, therefore, medically necessary when the following criterion is met:

- Disease is refractory to conservative medical therapy.
  - Conservative medical therapy may include, but is not limited to, the following:
    - Local hygiene and ordinary hygiene.
    - Use of antiseptic and antiperspirant agents (e.g., 6.25% aluminum chloride hexahydrate in absolute ethanol).
    - Application of warm compresses with sodium chloride solution or Burow solution.
    - Cessation of cigarette smoking.
    - Medical anti-inflammatory or antiandrogen therapy such as oral or topical antibiotics, intralesional triamcinolone, spironolactone, or finasteride.
    - Weight reduction in patients who are obese.
    - Wearing of loose-fitting clothing.
- Laser hair removal.

Limitations:

All other uses of surgery for HS are not medically necessary.

Alternative covered services:

- Primary care services (i.e., patient education)
- Specialty services (i.e., dermatologic service)

Background

HS is a chronic inflammatory skin condition characterized by recurrent painful boils in flexural sites (e.g., axillae and groin). HS is characterized by painful, recurrent nodules and abscesses that rupture and lead to sinus tracts and scarring in flexural sites (e.g., axillae and groin). HS affects about 1 percent of the general population, with onset in early adulthood. Its onset at the time of puberty has led several authorities to cite hormonal changes as an etiologic factor in the development of HS. Cigarette smoking also has a strongly positive correlation to the development of the condition.

The oldest, and simplest, system for classification of HS is the Hurley staging system. Hurley stage I is a single lesion without sinus tract formation. Stage II manifests as more than one lesion or area, but with limited tunneling. Stage III is defined as multiple lesions, with more extensive sinus tracts and scarring.

HS is difficult to treat owing to its pervasive inflammation with abscesses and inflammatory nodules, which leads to disruption of normal skin and subcutaneous architecture with sinus tract formation and, in severe cases, with extensive scarring. In contemporary practice, physicians often use the treatments below for HS:

- Antibiotics can reduce inflammation, fight infection, prevent HS from worsening, and stop new breakouts.
- Acne washes and medicines may be helpful, but these products alone usually will not clear HS.
- Bleach baths of 5 or 10 minutes are also useful as adjunctive therapy.

In refractory situations, a surgical procedure may be necessary:

- Incision and drainage. The surgeon drains one or two lesions or cuts them out. This can bring short-term relief, but the HS can return.
- Excision and primary closure (or deroofing) surgery may be an option for patients who have painful HS that repeatedly returns.
- Radical excision involves surgically cutting out the HS with a margin of normal-looking skin. Because the wound is deep, the area needs to be covered with a skin graft or a skin flap.
pulled from nearby skin to cover the wound.

Surgical excision aims to effect complete eradication of involved skin and subcutaneous tissues, and avert any possibility of malignant change (i.e., squamous carcinoma); however, controversy surrounds the best procedure. Moderately severe axillary lesions can be treated adequately by excision and primary closure. This approach is particularly popular because it allows both axillae to be treated simultaneously in the many patients with bilateral involvement.

**Searches**

AmeriHealth Caritas searched PubMed and the databases of:
- UK National Health Services Center 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 6, 2017. Search terms were: "hidradenitis suppurativa (MeSH)" and "surgery for hidradenitis suppurativa (MeSH)."

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**

Based on the European Dermatology Forum guidelines (Gulliver, 2016) for the management of HS, all patients should be offered adjuvant therapy as needed (pain management, weight loss, tobacco cessation, treatment of super-infections, and application of appropriate dressings). The treating physician should be familiar with disease severity scores, especially Hurley staging. The need for surgical intervention should be assessed in patients with higher Hurley stages of disease.

Humphries (2016) reviewed a single center’s 14-year experience of patients who underwent wide excision of HS between 2000 and 2014 with surgical treatment of chronic, severe HS through wide excision technique and healing by secondary intention. Attempts at removing all tissue affected by HS through wide surgical excision were the mainstay intervention for achieving complete local cure, particularly in the most severe cases of the disease. Seventeen patients underwent 23 separate surgical
encounters, five with excision of multiple areas. Seventeen excisional procedures were conducted on
the upper half of the body (axillary and breast) and 11 on the lower half (inguinal, perineum, perianal
and abdomen). Two patients developed HS recurrence adjacent to the surgical site (one requiring re-
excision and the other treated with topical therapy), whereas two developed HS flares at distant
nonsurgical sites managed medically. Wound care consisted of topical antimicrobials and hydrotherapy.
Physical therapy was initiated for joint contracture prevention. Patients were followed until complete
wound closure.

The mean follow-up was 1.02 years with a median of six months, ranging from 1.2 months to 5.25 years.
Complete wound healing ranged from eight weeks to 16 months, with limited range of motion (ROM) in
two patients. The authors concluded that wide excision of disease and healing by secondary intent
demonstrated clinically satisfactory functional and excellent aesthetic results in multiple anatomic areas
and even for large defects. They warned, however, that healing by secondary intention requires strict
adherence to a wound-care protocol, which is often tolerated only by patients who have endured
symptoms of severe HS for an extended length of time.

There is contemporary interest in a combined biologic and surgical approach to therapy for recalcitrant
HS. A study of combined therapy between 2011 and 2014 (DeFazio, 2015) described 21 patients (57
cases) with Hurley Stage III HS who underwent radical resection with delayed primary closure alone, or
in combination with adjuvant biologic therapy. Eleven patients underwent combined surgical and
biologic therapy, and radical resection alone was performed in 10 patients. The average soft tissue
deficit, before closure, for the combined and surgery-only patients was 56 cm and 48.5 cm, respectively
(P = 0.66). Biologic agents including infliximab (n = 8) and ustekinumab (n = 3) were initiated two to
three weeks after closure and were continued for an average of 10.5 months.

Recurrence was noted in 19 percent (4/29) and 38.5 percent (10/26) of previously treated sites for
combined and surgery-only patients (P < 0.01). For the combined cohort, the disease-free interval was
approximately one year longer on average (P < 0.001); however, this difference was reduced to 4.5
months when considering time to recurrence after cessation of biologic therapy (P = 0.09). New disease
developed in 18 percent (2/11) and 50 percent (5/10) of combined and surgery-only patients,
respectively (P < 001). No adverse events were noted among patients who received biologic therapy.
The authors concluded that lower rates of recurrence and disease progression, as well as a longer
disease-free interval, may be achieved with the use of adjuvant biologic therapy after radical resection
for recalcitrant HS.

Policy updates:

During the past twelve months there has been further information published regarding laser therapy for
HS.

A systematic review (John, 2016) of the effectiveness of various types of lasers (and light based
therapies) for the treatment of hidradenitis suppurativa (HS) found Nd:YAG laser to be effective for the
treatment of HS, as is intense pulsed light therapy (IPL) using the same principles of laser hair removal. There was only weak evidence to recommend the use of carbon dioxide, diode or alexandrite lasers.

**Summary of clinical evidence:**

<table>
<thead>
<tr>
<th>Citation</th>
<th>Content, Methods, Recommendations</th>
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<tbody>
<tr>
<td>John (2016)</td>
<td><strong>Key points:</strong></td>
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</tbody>
</table>
| A systematic review of the use of lasers for the treatment of hidradenitis suppurativa | - Systematic review of various types of lasers (and light based therapies) for the treatment of hidradenitis suppurativa (HS)  
- Found Nd:YAG laser and intense pulsed light therapy (IPL) are effective for the treatment of HS.  
- Insufficient evidence on carbon dioxide, diode or alexandrite lasers. |
| Van Rappard (2016)  | **Key points:**                   |
| Randomized controlled trials for the treatment of HS. | - HS is a chronic, inflammatory, recurrent, debilitating skin disease.  
- Several treatment modalities are available, but most of them lack high-quality evidence.  
- Evidence for long-term treatment and benefit/risk ratio of available treatment modalities is needed in order to enhance evidence-based treatment in daily clinical practice.  
- Combining surgery with anti-inflammatory treatment warrants further investigation. |
| Gulliver (2016)     | **Key points:**                   |
| Evidence-based approach to the treatment of HS/acro inversa, based on the European guidelines for HS. | - HS is a chronic inflammatory skin disease characterized by painful, recurrent nodules and abscesses that rupture and lead to sinus tracts and scarring.  
- To date, an evidence-based therapeutic approach has not been the standard of care and this is likely due to the lack of evidence-based treatment guidelines.  
- Based on the European Dermatology Forum guidelines for the management of HS, the diagnosis of HS should be made by a dermatologist or other health care professional with expert knowledge in HS.  
- All patients should be offered adjuvant therapy as needed (pain management, weight loss, tobacco cessation, treatment of super infections, and application of appropriate dressings).  
- The treating physician should be familiar with disease severity scores, especially Hurley staging, physician global assessment and others.  
- The need for surgical intervention should be assessed in all patients, depending on type and extent of scarring, and an evidence-based surgical approach should be implemented.  
- Future studies should include benefit risk ratio analysis, and long-term assessment of efficacy and safety, to facilitate long-term evidence-based treatment and rational pharmacotherapy. |
<p>| Humphries (2016)    | <strong>Key points:</strong>                   |
| Wide excision and healing by secondary intent for the surgical treatment of HS: a single-center experience. | - This study reviewed a single center's 14-year experience with surgical treatment of chronic, severe HS through wide excision technique and healing by secondary intention. |</p>
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| Janse (2016)     | • All patients who underwent wide excision of HS between 2000 and 2014 and allowed to heal by secondary intention were included. Wound care consisted of topical antimicrobials and hydrotherapy. Physical therapy was initiated for joint contracture prevention. Patients were followed until complete wound closure.  
• Seventeen patients underwent 23 separate surgical encounters, five with excision of multiple areas. Seventeen excisional procedures were conducted on the upper half of the body (axillary and breast) and 11 on the lower half (inguinal, perineum, perianus and abdomen).  
• Two patients developed HS recurrence adjacent to the surgical site (one requiring re-excision and the other treated with topical therapy), whereas two developed HS flares at distant nonsurgical sites managed medically.  
• The mean follow-up was 1.02 years with a median of six months, ranging from 1.2 months to 5.25 years.  
• Complete wound healing ranged from 8 weeks to 16 months, with limited ROM in two patients. |
| DeFazio (2015)   | **Key points:**  
• HS is difficult to treat owing to its complex pathomechanism; beside the extensive inflammation with abscesses and inflammatory nodules.  
• There is also an architectural loss with sinus tract formation and in severe cases with extensive scarring. |
| Hamzavi (2015)   | **Key points:**  
• Between 2011 and 2014, 21 patients (57 cases) with Hurley Stage III HS underwent radical resection with delayed primary closure alone, or in combination with adjuvant biologic therapy.  
• Eleven patients underwent combined surgical and biologic therapy, whereas radical resection alone was performed in 10 patients.  
• The average soft tissue deficit, before closure, for the combined and surgery-only patients was 56 cm and 48.5 cm, respectively (P = 0.66).  
• Biologic agents including infliximab (n = 8) and ustekinumab (n = 3) were initiated two to three weeks after closure and were continued for an average of 10.5 months.  
• Recurrence was noted in 19 percent (4/29) and 38.5 percent (10/26) of previously treated sites for combined and surgery-only patients (P < 0.01).  
• For the combined cohort, the disease-free interval was approximately one year longer on average (P < 0.001); however, this difference was reduced to 4.5 months when considering time to recurrence after cessation of biologic therapy (P = 0.09).  
• New disease developed in 18 percent (2/11) and 50 percent (5/10) of combined and surgery-only patients, respectively (P < 0.01).  
• No adverse events were noted among patients who received biologic therapy.  
• Lower rates of recurrence and disease progression, as well as a longer disease-free interval may be achieved with the use of adjuvant biologic therapy after radical resection for recalcitrant HS. |
| Laser and light-based | **Key points:**  
• Classically, pharmacologic and surgical therapies for HS have been effective for
treatment options for HS. reducing lesion activity and inflammation, but provide only modest success in the prevention of future recurrences and disease progression.

- Adjunctive therapies, such as laser and light-based therapies, have become more commonly used in the management of HS.
- These therapies work to reduce the occurrence of painful HS flare-ups by decreasing the number of hair follicles, sebaceous glands, and bacteria in affected areas, and by ablatively debulking chronic lesions.
- The best results are seen when treatment is individualized, taking disease severity into consideration when selecting specific energy-based approaches.

Kirby (2014) Health care utilization patterns and costs for patients with HS. Key points:

- A cohort cost-identification study of 16,736 individuals with claims for HS measured inpatient length of stay, emergency department and outpatient visits, and number of days supplied of prescription medication.
- The largest component of the total three-year cost for the HS group was inpatient cost (37.4 percent).
- The proportion of people who were hospitalized in the HS cohort (15.8 percent) was higher than control (8.6 percent) groups (P < .001).
- The proportion of patients who sought emergency room (ER) care over the three-year period was higher in the HS cohort (27.1 percent) than in the control group (17.2 percent) (P < .001), with the mean three-year ER cost for the HS group of $2,002.

References

Professional society guidelines/other:


Peer-reviewed references:


Humphries LS, Kueberuwa E, Beederman M, Gottlieb LJ. Wide excision and healing by secondary intent


**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 in accordance with those manuals.

<table>
<thead>
<tr>
<th>CPT Code</th>
<th>Description</th>
<th>Comment</th>
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<tbody>
<tr>
<td>10060</td>
<td>Incision and drainage of abscess (eg, carbuncle, suppurative hidradenitis, cutaneous or subcutaneous abscess, cyst, furuncle, or paronychia); simple or single</td>
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<td>11450</td>
<td>Excision of skin and subcutaneous tissue for hidradenitis, axillary; with simple or intermediate repair</td>
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<tr>
<td>11451</td>
<td>Excision of skin and subcutaneous tissue for hidradenitis, axillary; with complex repair</td>
<td></td>
</tr>
<tr>
<td>11462</td>
<td>Excision of skin and subcutaneous tissue for hidradenitis, inguinal; with simple or intermediate repair</td>
<td></td>
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<tr>
<td>11463</td>
<td>Excision of skin and subcutaneous tissue for hidradenitis, inguinal; with complex repair</td>
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<tr>
<td>11470</td>
<td>Excision of skin and subcutaneous tissue for hidradenitis, perianal, perineal, or umbilical; with simple or intermediate repair</td>
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<tr>
<td>11471</td>
<td>Excision of skin and subcutaneous tissue for hidradenitis, perianal, perineal, or umbilical; with complex repair</td>
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<table>
<thead>
<tr>
<th>ICD-10 Code</th>
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