Policy

I. Aetna considers medicinal leech (Hirudo medicinalis) therapy medically necessary for any of the following conditions:

A. Poor venous drainage (venous congestion/venous outflow obstruction); or
B. Salvage of vascularly compromised flaps (muscle, skin, and fat tissue surgically removed from one part of body to another); or
C. Salvage of vascularly compromised replants (limbs or other body parts re-attached after traumatic amputation).

II. Aetna considers medicinal leech therapy experimental and investigational for treating cancer pain, epidermoid cysts (also called epidermal cysts or epidermal inclusion cysts), knee osteoarthritis, inadequate arterial supply or tissue ischemia, rheumatoid arthritis and other musculoskeletal diseases, and for all other indications because of insufficient
evidence of its safety and effectiveness.

III. Aetna considers medical maggots medically necessary for the debridement of any of the following non-healing necrotic skin and soft tissue wounds:

A. Neuropathic foot ulcers; or
B. Non-healing traumatic or post surgical-wounds; or
C. Pressure ulcers; or
D. Venous stasis ulcers.

IV. Aetna considers bagged larval therapy an equally effective medically necessary alternative to medical maggot therapy.

V. Aetna considers bagged larval therapy/medical maggots experimental and investigational for all other indications (e.g., chronic diabetic foot wounds and hand injury complicated by mycotic infection) because of insufficient evidence of its safety and effectiveness

**Background**

**Medicinal Leech Therapy:**

The medicinal leech, *Hirudo medicinalis*, has been used increasingly for relief of venous congestion, especially for salvage of compromised pedicled flaps and microvascular free-tissue transfer, digital re-implantation, and breast reconstruction. Leech therapy for compromised flaps is best used early since flaps demonstrate significantly decreased survival after 3 hours if venous congestion is not relieved. If venous pooling occurs around a flap or replant, the skin becomes cyanotic, cool, and hard. If capillary refill time (CRT) remains more than 3 seconds the flap or replant will not survive. The objective of leech therapy is for the affected area to become pink and warm, with a CRT of less than 2 seconds.
When leeches begin feeding, they inject salivary components (e.g., hirudin) that inhibit both platelet aggregation and the coagulation cascade. This results in a marked relief of venous congestion. The anti-coagulant causes the bite to ooze for up to 48 hours following detachment, further relieving venous congestion. By feeding for 10 to 60 mins, leeches consume from 1 to 2 teaspoons of blood. Results from clinical studies showed that the success rate of salvaging tissue with medicinal leech therapy is 70 to 80%. On June 28, 2004, the Food and Drug Administration (FDA) had for the first time cleared the commercial marketing of leeches for medicinal purposes (in skin grafts and re-attachment surgery).

Recently, leech therapy has also been suggested to be an effective treatment for rapid reduction of pain associated with osteoarthritis of the knee (Michalsen et al, 2002). However, its effectiveness in treating osteoarthritis (OA) of the knee needs to be validated in larger randomized controlled studies. In a follow-up randomized controlled study, Michalsen et al. (2003) evaluated the effectiveness of leech therapy for symptomatic relief of patients with OA of the knee (n = 51). Patients received a single treatment with 4 to 6 locally applied leeches (leech therapy group) or a 28-day topical diclofenac regimen (control group). The primary end point, pain at day 7, was reduced from a mean (+/- SD) of 53.5 +/- 13.7 to 19.3 +/- 12.2 after leech therapy compared with 51.5 +/- 16.8 to 42.4 +/- 19.7 with topical diclofenac. Although the difference between group pain scores was no longer significant after day 7, differences for function, stiffness, and total symptoms remained significant in favor of leech therapy until the end of study and for quality of life until day 28. The authors concluded that leech therapy helps relieve symptoms in patients with OA of the knee. The potential of leech therapy for treating OA and the pharmacological properties of leech saliva remain to be clarified.

In an editorial that accompanied the article by Michalsen et al, Hochberg (2003) discussed some of the drawbacks of this paper. A lack of blinding of the patients as well as the
researchers is a major pitfall because it raises concerns regarding measurement bias, especially since the outcome measures were all subjective. Also, 7 days is a short time frame for measuring the primary outcome measure since OA is a chronic condition. Furthermore, patients in both groups seldom used rescue therapy, suggesting that, despite the observed significant differences in pain scores at day 7, both groups may have been satisfied with their responses to study interventions. Thus, it is still unclear whether leech therapy is effective in treating knee pain in patients with OA.

In an unblinded, randomized controlled trial with outpatients in a cross-over design with single interventions of either leeches or transcutaneous electrical nerve stimulation (TENS) as comparator, Stange and colleagues (2012) evaluated the possible efficacy of medical leeches in the treatment of patients with active OA of the knee. Main outcome measures were change in Lequesne's combined index for pain and function and change (L.I.) and overall assessment of complaints by VAS. Cross-over at day 42, with further observation period of 21 days. A total of 52 out of 72 screened patients were randomized (intent-to-treat) to initial treatment with either 8 leeches (group 1; n = 27 patients) or TENS (group 2; n = 25 patients). Due to phase effects, confirmatory evaluation had to be restricted to the first period. Between days 0 and 21, these researchers observed highly significant (p < 0.001) improvements for means of Lequesne's index from 12.07 to 9.37 and for VAS from 5.89 to 4.16 cm for leeches, but no significant differences for TENS. Effect size as group difference was -2.50 for L.I. (95 % CI: -3.88 to -1.11), resp. -1.86 cm for VAS (95 % CI: -2.85 to -0.87 cm). A total of 12 patients (5 in group 1, and 7 in group 2) did not finish the trial, mostly due to non-compliance (n = 6). No serious adverse effects were observed. The authors concluded that single leech therapy showed significant, relevant and sustaining effects, comparable to other trials with leeches. They stated that the method deserves further research, especially into mechanisms of possible specific effects and optimization of dosing by number of leeches and possible repeats.
Lauche and colleagues (2014) carried out a systematic review and meta-analysis of the effectiveness of medical leech therapy for OA of the knee. The PubMed/MEDLINE, Cochrane Library, EMBASE, Scopus, and CAMBASE databases were screened in August 2012 to identify randomized (RCTs) and non-randomized controlled clinical trials (CCTs) comparing leech therapy to control conditions. Main outcome measures were pain, functional impairment, and joint stiffness. For each outcome, standardized mean differences (SMD) and 95% CIs were calculated. A total of 3 RCTs and 1 CCT were found, in which a total of 237 patients with osteoarthritis were included. Three trials had a low risk of bias. There was strong overall evidence for immediate (SMD = -1.05; p < 0.01) and short-term pain reduction (SMD = -1.00; p < 0.01), immediate improvement in patients' physical function (SMD = -0.72; p < 0.01), and both immediate (SMD = -0.88; p = 0.04) and long-term improvement in their joint stiffness (SMD = -0.62; p < 0.01). Moderate evidence was found for leech therapy's short-term effects on physical function (SMD = -0.46; p < 0.01) and long-term effects on pain (SMD = -0.45; p < 0.01). Leech therapy was not associated with any serious adverse events. The authors concluded that this systematic review found moderate to strong evidence for the reduction of pain, functional impairment, and joint stiffness after medical leech therapy in patients with OA of the knee. They stated that given the low number of reported adverse events, leech therapy may be a useful approach in treating this condition. Moreover, they stated that further high-quality RCTs are needed for the conclusive judgment of its safety and effectiveness.

Kalender and colleagues (2010) reported a case of severe pain related to advanced stage cancer successfully treated by self-applied leeches. A 62-year old male patient with synchronous renal cell carcinoma and leiomyosarcoma was admitted with severe pain in the lumbar region. The pain was refractory to radiotherapy, and systemic and epidural analgesic infusion. After 2 months, the patient came to the clinic in good condition free of pain. The patient reported outpatient self-treatment with 7 leeches to the lumbar region in the
interim that resulted in complete healing of pain. The authors concluded that this is the first report indicating possible activity of leeches in cancer pain. The finding of this case report needs to be validated by well-designed studies.

Rasi and colleagues (2014) observed a healthy 64-year old Iranian man, who presented with numerous asymptomatic multi-lobular oval-to-round well-defined 0.5 to 1.5 cm cystic lesions with central umbilication (central black eschar) over the upper portion of his chest. These investigators made the diagnosis of epidermoid cyst, giant comedone and leech bite on the basis of the constellation of clinical features. The patient was treated with oral ciprofloxacin at a dose of 2 g daily, and 2% topical erythromycin solution. Despite improvement, the evidence of cystic lesions persisted. There was no history of similar lesions in any other family member. There was no history of trauma. The patient was not using any topical or systemic medication. Two weeks before his visit, he had a history of leech therapy under the supervision of a general practitioner. His medical history was significant for leech therapy of the lesions, 5 days previously. He was followed-up for another 2 weeks and after disappearance of the inflammation, with the patient under local anesthesia, the well-circumscribed mass was completely evacuated with a sharp curette and comedone extractor. The patient was subsequently lost to follow-up. The authors concluded that considering the effectiveness of leeches, it would be favorable to breed a germ-free leech. In Iran, the use of the leeches in surgery, in recent years, has been infrequent. It appears that the positive effects of this ancient remedy may now be explained through scientific methods, promising potentially even more uses of this admirable creature in medicine.

Furthermore, an UpToDate review on “Overview of benign lesions of the skin” (Goldstein and Goldstein, 2014) does not mention the use of medicinal leech therapy as a therapeutic option for epidermoid cysts (also called epidermal cysts or epidermal inclusion cysts).
In a review on “Conservative treatment of thumb base osteoarthritis”, Spaans et al (2015) stated that there is insufficient evidence justifying the use of leech therapy.

An UpToDate review on “Complementary and alternative remedies for rheumatic disorders” (Panush, 2015) stated that “A list of all “non-mainstream” therapies touted for patients with rheumatic and musculoskeletal diseases would be extensive indeed. Prominent "complementary" and "alternative" remedies for rheumatic disorders include .... Newer biologic agents, such as monoclonal antibodies and interventions that perturb function of interleukins, cytokines, and similar mediators of inflammation/pain/immune responses, are exciting because of their therapeutic potential. These are not usually considered "alternative" remedies, but it bears noting that until safety and efficacy are established, they are not evidence-based mainstream therapies. Additional "complementary" and "alternative" remedies include other therapies (leeches, botulinus toxin, prayer, Ayurvedic medicine, and sitting in abandoned uranium mines) .... Pain relief from the application of leeches was reported in a study of 51 patients with osteoarthritis who were randomly assigned to have leeches (Hirudo medicinalis) or topical diclofenac applied to an affected knee [citing Michelson, et al., 2003). Significantly more pain relief was reported with leeching than with diclofenac when assessed at seven days. The benefit persisted for up to 28 days and was associated with improvements in stiffness and function. The lack of blinding of patients and assessors is a major potential source of bias and diminishes confidence in the results. Use of leeches also carries a risk of cellulitis and septicemia due to Aeromonas hydrophilia that colonize medicinal leeches”.

Medicinal leech therapy is usually carried out for 4 to 5 days for patients with replant; it may be performed for 6 to 10 days for patients with compromised flaps.

A complication of leech therapy is the risk of infection; thus, it is recommended that therapy not be used in the presence of
non-viable tissue.

Patients with HIV infection, or individuals taking immunosuppressive medications should not undergo leech therapy because of the risk of overwhelming bacterial sepsis.

**Medical Maggots:**

During the 1930s, maggot debridement therapy (MDT) was used routinely for treating bone and soft tissue infections. Its use was supplanted by the introduction of new antibiotics and improvements in wound care. Recently, however, there has been a resurgence in the use of maggot therapy.

Medical maggots are blow fly (i.e., *phaenicia sericata*) larvae. Medical maggots, or larval therapy, is also known as maggot therapy, maggot dressings, green blow fly maggots, bio-surgery, disinfected maggots, sterile maggots, therapeutic maggots, debriding maggots, maggot debridement therapy, or MDT dressings. Medical maggots secret digestive enzymes that selectively dissolve necrotic tissue, disinfect the wound, and stimulate wound healing.

Medical maggots received 510(k) marketing clearance by the FDA and are intended to debride non-healing necrotic skin and soft tissue wounds, including pressure ulcers, venous stasis ulcers, neuropathic foot ulcers, and non-healing traumatic or post-surgical wounds. According to information submitted by the manufacturer to the FDA, the fly eggs are chemically disinfected before being placed in sterile vials for transport. The dressings used to confine them on the wound are called "Creature Comforts" and are designed to create a confining "cage dressing." They are applied directly to the wound surface in a dose of 5 to 8 maggots per square cm. The dressings are left in place on the wound for a "cycle" of 48 hours (24 to 72 hours); 1 to 3 cycles are applied weekly. Most wounds require 2 to 6 cycles for complete debridement.

In a prospective study, Sherman et al (1995) evaluated the
utility of maggot therapy (MT) for treating pressure ulcers in spinal cord injury patients. Eight patients received MT after a baseline assessment of healing under conventional therapy (defined as any therapy prescribed by the patient's primary care team). Surface area, tissue quality and healing rates were monitored weekly. Maggot therapy debrided most of the necrotic wounds within 1 week, which was more rapid than all other non-surgical methods. Wound healing was more rapid during MT than during antecedent conventional therapy (p = 0.01). No complications were noted.

In an abstract presented during the European Association for the Study of Diabetes Annual Meeting (2000), Markevich et al reported the results of a 30-month randomized, multi-center, double-blind controlled clinical trial of MT for diabetic neuropathic foot wounds as compared with conventional modern treatment in 140 diabetic patients. Sterile maggots (larvae) of the green-bottle fly (Lucilia sericata) were applied to the wound (6 to 10 per square cm) for 72 hours. At 10 days, granulation tissue covered greater than 50% of the wound in the MT group versus 34% in the control, and the wound area had decreased by greater than 50% in the MT group versus 27% in the control. This may be a useful method for debridement of necrotic tissue from diabetic foot wounds with particular benefits in stimulating tissue growth and improving the rate of healing (Bloomgarden, 2001).

Wayman et al (2000) examined the clinical efficacy and cost effectiveness of larval therapy in the debridement of sloughy venous ulcers. A total of 12 patients with sloughy venous ulcers were randomized to receive either larval debridement therapy (LDT) or a hydrogel (the control). Effective debridement occurred with a maximum of 1 larval application in 6/6 patients; 4/6 patients in the hydrogel group still required dressings at 1 month. The median cost of treatment of the larval group was 78.64 pounds compared with 136.23 pounds for the control treatment group (p < 0.05).

Sherman (2002) compared MT versus conservative
Debridement therapy for the treatment of pressure ulcers in 103 in-patients with 145 pressure ulcers. A total of 61 ulcers in 50 patients received MT at some point during their monitored course and 84 ulcers in 70 patients did not. Debridement and wound healing could be quantified for 43 maggot-treated wounds and 49 conventionally treated wounds. Eighty percent of maggot-treated wounds were completely debrided, while only 48% of wounds were completely debrided with conventional therapy alone (p = 0.021). Within 3 weeks, maggot-treated wounds contained 1/3 the necrotic tissue (p = 0.05) and twice the granulation tissue (p < 0.001), compared to non-maggot-treated wounds. Of the 31 measurable maggot-treated wounds monitored initially during conventional therapy, necrotic tissue decreased 0.2 square cm per week during conventional therapy, while total wound area increased 1.2 square cm per week. During maggot therapy, necrotic tissue decreased 0.8 square cm per week (p = 0.003) and total wound surface area decreased 1.2 square cm per week (p = 0.001).

The author concluded that MT was more effective and efficient in debriding chronic pressure ulcers than the conventional treatments prescribed, patients readily accepted MT and adverse events were uncommon.

Sherman (2003) retrospectively assessed the efficacy of MT for treating foot and leg ulcers in 18 diabetic patients who failed conventional therapy. Of the 20 non-healing ulcers, 6 wounds were treated with conventional therapy, 6 with MT, and 8 with conventional therapy first, then MT. Repeated measures ANOVA indicated no significant change in necrotic tissue, except when factoring for treatment (F[1.7, 34] = 5.27, p = 0.013). During the first 14 days of conventional therapy, there was no significant debridement of necrotic tissue; during the same period with MT, necrotic tissue decreased by an average of 4.1 square cm (p = 0.02). After 5 weeks of therapy, conventionally treated wounds were still covered with necrotic tissue over 33% of their surface, whereas after only 4 weeks of therapy maggot-treated wounds were completely debrided (p = 0.001). Maggot therapy was also associated with hastened growth of granulation tissue and greater wound healing rates.
Sherman and Shimoda (2004) evaluated post-operative complications of pre-surgical wounds treated with MDT versus a matched group of patients who were not treated with MDT. Ten wounds were debrided by maggots within 1 to 17 days before surgical closure. Debridement was effective in all cases, and there were no post-operative wound infections. Six (32 %) of 19 wounds not treated pre-surgically with MDT developed post-operative wound infections (95 % confidence interval [CI]: 10 % to 54 %; p < 0.05). Pre-surgical MDT was effective in preparing the wound bed for surgical closure, without increased risk of post-surgical wound infection.

Armstrong et al (2005) assessed MDT in 60 non-ambulatory patients (mean age of 72.2 years) with neuro-ischemic diabetic foot wounds and peripheral vascular disease. Twenty-seven of these patients (45 %) healed during 6 months of review. There was no significant difference in the proportion of patients healing in the MDT versus control group (57 % versus 33 %). Of patients who healed, time to healing was significantly shorter in the MT than in the control group (18.5 +/- 4.8 versus 22.4 +/- 4.4 weeks). Approximately 1 in 5 patients (22 %) underwent a high-level (above-the-foot) amputation. Patients in the control group were 3 times as likely to undergo amputation (33 % versus 10 %). Although there was no significant difference in infection prevalence in patients undergoing MT versus controls (80 % versus 60 %), there were significantly more antibiotic-free days during follow-up in patients who received MT (126.8 +/- 30.3 versus 81.9 +/- 42.1 days). Maggot debridement therapy reduced short-term morbidity in non-ambulatory patients with diabetic foot wounds.

Tantawi et al (2007) assessed the clinical and microbiological efficacy of MDT in the management of diabetic foot ulcers unresponsive to conventional treatment and surgical intervention. Consecutive diabetic patients with foot wounds were selected for MDT. Lucilia sericata medicinal maggots were applied to the ulcers for 3 days per week. Changes in the percentage of necrotic tissue and ulcer surface area were recorded each week over the 12-week follow-up period.
Semi-quantitative swab technique was used to determine the bacterial load before and after MDT. The sample comprised 10 patients with 13 diabetic foot ulcers. The mean baseline ulcer surface area was 23.5 square cm (range of 1.3 to 63.1) and the mean percentage of necrotic tissue was 74.9 % (range of 29.9 to 100). Complete debridement was achieved in all ulcers in a mean of 1.9 weeks (range of 1 to 4). Five ulcers (38.5 %) were completely debrided with one 3-day MDT cycle. The mean reduction in ulcer size was significant at 90.2 % and this occurred in a mean of 8.1 weeks (range of 2 to 12). The mean weekly reduction in ulcer size was 16.1 % (range of 8.3 to 50). Full wound healing occurred in 11 ulcers (84.6 %) within a mean of 7.3 weeks (range of 2 to 10). The bacterial load of all ulcers reduced sharply after the first MDT cycle to below the $10^5$ threshold, which facilitates healing. The authors concluded that the results highlight the potential benefits of MDT in diabetic wound care in developing countries and that MDT proved to be a rapid, simple and efficient method of treating these ulcers.

A review of MDT in chronic wound care by Chan et al (2007) stated that MDT has been shown to be a safe and effective means of chronic wound management, however, there are a number of limitations when considering its local applicability. Future development of the delivery system may help to overcome some of these limitations and improve its acceptability.

The VenUS II trial, a multi-center prospective clinical study compared the clinical and cost-effectiveness of 2 types of larval therapy (loose and bagged) with a standard debridement intervention (hydrogel). Patients ($n = 267$) with at least 1 venous or mixed venous and arterial ulcer with at least 25 % coverage of slough or necrotic tissue, and an ankle brachial pressure index of 0.6 or more were enrolled in the study. The primary outcome was time to healing of the largest eligible ulcer. Secondary outcomes were time to debridement, health related quality of life (SF-12), bacterial load, presence of methicillin resistant Staphylococcus aureus (MRSA), adverse events, and ulcer related pain (VAS, from 0 mm for no pain to
150 mm for worst pain imaginable). The authors reported that time to healing was not significantly different between the loose or bagged larvae group and the hydrogel group (hazard ratio for healing using larvae versus hydrogel 1.13, 95 % CI: 0.76 to 1.68; p = 0.54). Larval therapy reduced the time to debridement (hazard ratio 2.31, 95 % CI: 1.65 to 3.2; p < 0.001). Health related quality of life and change in bacterial load over time were not significantly different between the groups. Seven percent of participants had MRSA at baseline and there was no difference found between larval therapy and hydrogel in their ability to eradicate MRSA by the end of the debridement phase (75 % (9/12) versus 50 % (3/6); p = 0.34), although this comparison was under-powered. Mean ulcer related pain scores were higher in either larvae group compared with hydrogel (mean difference in pain score: loose larvae versus hydrogel 46.74 (95 % CI: 32.44 to 61.04), p < 0.001; bagged larvae versus hydrogel 38.58 (23.46 to 53.70), p < 0.001). The authors concluded that larval therapy did not improve the rate of healing of sloughy or necrotic leg ulcers or reduce bacterial load compared with hydrogel and was associated with significantly more ulcer related pain, but it did significantly reduce the time to debridement compared with hydrogel (Dumville et al, 2009).

To assess the cost-effectiveness of larval therapy compared with hydrogel in the management of leg ulcers, Soares et al (2009) carried out a cost-effectiveness and cost utility analyses alongside the VenUS II trial. The time horizon was 12 months and costs were estimated from the United Kingdom National Health Service perspective. Cost-effectiveness outcomes were expressed in terms of incremental costs per ulcer-free day (cost effectiveness analysis) and incremental costs per quality adjusted life years (cost utility analysis). The larvae arms were pooled for the main analysis. Treatment with larval therapy cost, on average, pound 96.70 (Euro 109.61; $140.57) more per participant per year (95 % CI: - pound 491.9 to pound 685.8) than treatment with hydrogel. Participants treated with larval therapy healed, on average, 2.42 days before those in the hydrogel arm (95 % CI: -0.95 to 31.91 days) and had a slightly
better health related quality of life, as the annual difference in QALYs was 0.011 (95% CI: -0.067 to 0.071). However, none of these differences was statistically significant. The incremental cost-effectiveness ratio for the base case analysis was estimated at pound 8,826 per QALY gained and pound 40 per ulcer-free day. Considerable uncertainty surrounds the outcome estimates. The authors concluded that debridement of sloughy or necrotic leg ulcers with larval therapy is likely to produce similar health benefits and have similar costs to treatment with hydrogel.

Guidance from the National Institute for Clinical Excellence (NICE, 2001) on the use of debriding agents for difficult to treat surgical wounds addressed the use of maggot therapy and other agents. The guidance states that there is no randomized controlled trial evidence to support any particular method of debridement for difficult to heal surgical wounds, but less robust studies suggest modern dressings (products thought to promote autolytic wound debridement, including hydrocolloids, hydrogels, polysaccharide beads/paste, foam dressings, and alginate dressings) as well as bio-surgical techniques (sterile maggots) may reduce pain and be more acceptable to patients. The guidance stated that, in the absence of sufficient evidence for or against any particular method of debridement, or for one type of modern dressing over another, the choice of debriding agent for difficult to heal surgical wounds should be based on impact on comfort, odor control and other aspects relevant to patient acceptability, type and location of wound, and total costs.

Igari et al (2013) noted that maggots are potent debriding agents capable of removing necrotic tissue and slough; however, it is still unclear which wounds are most likely to benefit from MDT. These researchers performed a retrospective review to gain insight into the patient and therapy characteristics influencing outcome. They reviewed patients with foot ulcers caused by critical limb ischemia, encountered during the period between June 2005 and May 2010. The treatment outcomes were defined as effective or ineffective.
There were 16 patients with 16 leg ulcers. The patients were 13 men and 3 women, with an average age of 67.2 years (range of 47 to 85 years). Ten (63%) of the 16 ulcers were treated effectively. According to univariate analyses, an ankle brachial pressure index (ABI) lower than 0.6 (\( p = 0.03 \)) had a negative impact on the outcome of MDT; however, outcome was not influenced by gender, obesity, ischemic heart disease, diabetes mellitus, hemodialysis, smoking, or laboratory findings. The authors concluded that some patient characteristics, such as gender, obesity, ischemic heart disease, diabetes mellitus, hemodialysis, and smoking, do not seem to contraindicate eligibility for MDT. However, a limb with an ABI lower than 0.6 is less likely to benefit.

Chronic Diabetic Foot Wounds:

Shi and Shofler (2014) stated that maggot debridement therapy is used extensively in the United Kingdom in both community and hospital situations, but remains a potentially under-used modality in many wound care markets. It promotes wound healing by performing 3 key processes: (i) debridement, (ii) disinfection and (iii) growth-promoting activity. It can be used for the debridement of non-healing necrotic skin and soft tissue wounds, including pressure ulcers, venous stasis ulcers, neuropathic foot ulcers and non-healing traumatic post-surgical wounds. The authors stated that with the increase in chronic diabetic foot wounds, maggot debridement therapy is a promising tool for health professionals dealing with difficult wounds.

Furthermore, UpToDate reviews on “Clinical manifestations, diagnosis, and management of diabetic infections of the lower extremities” (Weintrob and Sexton, 2016), “Management of diabetic foot ulcers” (McCulloch et al, 2016), and “Overview of treatment of chronic wounds” (Evans and Kim, 2016) do not mention the use of maggot as a therapeutic option for chronic diabetic foot wounds.
Bohac and colleagues (2015) noted that complex injuries of the hand remain a therapeutic challenge for surgeons. These researchers presented the case of a male who suffered a devastating injury of the hand caused by a conveyor belt. The patient developed a progressive Absidia corymbifera infection of the affected soft tissues. Initial treatments with serial surgical debridement and topical and intravenous itraconazole were unsuccessful in eliminating the infection. These investigators used maggot debridement therapy in a new special design to debride all necrotic, devitalized tissue and preserve only healthy tissue and functioning structures. This maneuver followed by negative pressure therapy (NPT) allowed progressive healing. The authors concluded that in such complex hand injuries, maggot debridement combined with negative pressure therapy could be considered to achieve effective and considerable results, although future functional morbidity may occur. This was a single-case study; and its findings were confounded by the combined use of maggot and NPT. These preliminary findings need to be validated by well-designed studies.

Also, an UpToDate reviews on “Overview of hand infections” (Sebastin et al, 2016), does not mention the use of maggot as a therapeutic option.

### CPT Codes / HCPCS Codes / ICD-10 Codes

*Information in the [brackets] below has been added for clarification purposes. Codes requiring a 7th character are represented by "+":*

ICD-10 codes will become effective as of October 1, 2015:

**Medicinal leech therapy:**

There is no specific CPT code for medicinal leech therapy:

ICD-10 codes covered if selection criteria are met:

<table>
<thead>
<tr>
<th>ICD-10 Code</th>
<th>Description</th>
</tr>
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<tbody>
<tr>
<td>I87.1</td>
<td>Compression of vein</td>
</tr>
<tr>
<td>I87.2</td>
<td>Venous insufficiency (chronic) (peripheral)</td>
</tr>
<tr>
<td>I99.8</td>
<td>Other disorder of circulatory system</td>
</tr>
<tr>
<td>ICD-10 Code</td>
<td>Description</td>
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<tr>
<td>------------------</td>
<td>-------------------------------------------------------</td>
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<tr>
<td>T86.820 - T86.829</td>
<td>Complications of skin graft (allograft) (autograft)</td>
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<tr>
<td>T87.0x1 - T87.2</td>
<td>Complications of reattached extremity or body part</td>
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<tr>
<td>Z89.011 - Z89.9</td>
<td>Acquired absence of limb</td>
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**ICD-10 codes not covered for indications listed in the CPB:**

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<th>Code</th>
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<tr>
<td>B20</td>
<td>Human immunodeficiency virus [HIV] disease</td>
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<tr>
<td>D80.0 - D89.9</td>
<td>Certain disorders involving the immune mechanism</td>
</tr>
<tr>
<td>G89.3</td>
<td>Neoplasm related pain (acute) (chronic)</td>
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<tr>
<td>L72.0</td>
<td>Epidermal cyst</td>
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<tr>
<td>M00.00 - M99.9</td>
<td>Diseases of the musculoskeletal system and connective tissue</td>
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<tr>
<td>M17.0 - M17.9</td>
<td>Osteoarthrosis of knee</td>
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<tr>
<td>Z21</td>
<td>Asymptomatic human immunodeficiency virus [HIV] infection status</td>
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**Medical maggots:**

**CPT codes covered if selection criteria are met:**

<table>
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<th>Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>97602</td>
<td>Removal of devitalized tissue from wound(s), non-selective debridement, without anesthesia (eg, wet-to-moist dressings, enzymatic, abrasion), including topical application(s), wound assessment, and instruction(s) for ongoing care, per session</td>
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**ICD-10 codes covered if selection criteria are met:**

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<tr>
<th>Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>E08.610 - E08.69</td>
<td>Diabetes mellitus due to underlying condition with other specified complications</td>
</tr>
<tr>
<td>E09.610 - E09.69</td>
<td>Drug or chemical induced diabetes mellitus with other specified complications</td>
</tr>
<tr>
<td>E10.610 - E10.69</td>
<td>Type 1 diabetes mellitus with other specified complications</td>
</tr>
<tr>
<td>E11.610 - E11.69</td>
<td>Type 2 diabetes mellitus with other specified complications</td>
</tr>
</tbody>
</table>
The above policy is based on the following references:

**Medicinal Leech Therapy**


Medical Maggots


15. Chan DC, Fong DH, Leung JY, et al. Maggot debridement
28. McCulloch DK, de Asla RJ, Armstrong DG. Management of
diabetic foot ulcers. UpToDate Inc., Waltham, MA. Last reviewed March 2016.

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Amendment to
Aetna Clinical Policy Bulletin Number: 0556
Bio-Surgery: Medicinal Leech Therapy and Medical Maggots

There are no amendments for Medicaid.