

<b>2.01.105</b>	<b>Dry Hydrotherapy for Chronic Pain Conditions</b>		
<b>Original Policy Date:</b>	August 1, 2022	<b>Effective Date:</b>	August 1, 2022
<b>Section:</b>	2.0 Medicine	<b>Page:</b>	Page 1 of 7

## Policy Statement

- I. The use of dry hydrotherapy massagers for the treatment of chronic pain conditions is considered **investigational**.

**NOTE:** Refer to [Appendix A](#) to see the policy statement changes (if any) from the previous version.

## Policy Guidelines

- N/A

## Description

Dry hydrotherapy, also known as hydromassage or aquamassage, is a massage treatment modality that circulates heated, pressurized water in a self-contained device such as a bed or chair. The individual remains clothed and dry as they sit or lie on top of a waterproof barrier containing rotating and pulsating interior jets. Purported benefits of dry hydrotherapy include alleviation of pain, increased blood circulation, improved range of motion, and decreased need for other interventions.

## Related Policies

- Manipulation Under Anesthesia
- Medical Cannabis for the Treatment of Pain and Spasticity
- Paraspinal Surface Electromyography to Evaluate and Monitor Back Pain
- Trigger Point and Tender Point Injections

## Benefit Application

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

Some state or federal mandates (e.g., Federal Employee Program [FEP]) prohibits plans from denying Food and Drug Administration (FDA)-approved technologies as investigational. In these instances, plans may have to consider the coverage eligibility of FDA-approved technologies on the basis of medical necessity alone.

## Regulatory Status

Dry hydrotherapy devices are classified by the U.S. Food and Drug Administration (FDA) as class I therapeutic massagers, which are defined as electrically powered devices intended for medical purposes, such as to relieve minor muscle aches and pains. Class I devices are exempt from 510(k) requirements and do not require submission of clinical data regarding efficacy but only notification of the FDA prior to marketing (FDA Product Code: ISA; Sec. 890.5660).

Dry hydrotherapy does not involve water immersion and should not be confused with immersion hydromassage baths or powered sitz baths (FDA Product Code: ILJ; Sec. 890.5100).

Examples of currently marketed dry hydrotherapy devices include but may not be limited to HydroMassage branded (previously AquaMED) beds and loungers (JTL Enterprises Inc.),<sup>2</sup> Massage Time Pro S10 or ComfortWave S10 branded hydromassage tables (Sidmar Manufacturing Inc.),<sup>3</sup> and SolaJet® Dry-Hydrotherapy Systems.<sup>4</sup>

## Rationale

### Background

#### Dry Hydrotherapy

Dry hydrotherapy, also known as hydromassage or aquamassage, is a massage treatment modality that circulates streams of heated, pressurized water in a self-contained device such as a bed or chair. The individual remains clothed and dry as they sit or lie on top of a waterproof barrier containing rotating and pulsating interior jets. Purported benefits of dry hydrotherapy include alleviation of pain, increased blood circulation, improved range of motion, deep relaxation, and reduction of stress and anxiety. Use of dry hydrotherapy has also been suggested to reduce the need for other interventions, by combining the effects of traditional wet hydrotherapy, massage therapy, acupuncture, heat therapy, soft tissue manipulation, and trigger point therapy without the need for additional health staff.

Specific physiological effects claimed on the Sidmar manufacturer site for its hydromassage tables include purported physiological effects stemming from application of radiant heat and massage.<sup>1</sup> Purported physiologic effects of radiant heat include analgesic, antispasmodic, decongestive, sedative, and vasodilatory properties, leading to reduced pain, increased relaxation, enhanced capillary blood flow, decreased spasticity, tenderness, and spasm, and increased rates of healing. Purported benefits of massage include increased local blood supply, increased lymphatic drainage and reduction of swelling, muscle relaxation, prevention of adhesions and fibrosis, decreased tendency toward muscle atrophy, and pain reduction and increased ease of mobility.

### Literature Review

Evidence reviews assess the clinical evidence to determine whether the use of a technology improves the net health outcome. Broadly defined, health outcomes are length of life, quality of life, and ability to function including benefits and harms. Every clinical condition has specific outcomes that are important to patients and to managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of a technology, 2 domains are examined: the relevance and the quality and credibility. To be relevant, studies must represent 1 or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial (RCT) is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. Randomized controlled trials are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

## Dry Hydrotherapy for Chronic Pain Conditions

### Clinical Context and Therapy Purpose

The purpose of dry hydrotherapy is to provide a treatment option that is an alternative to or an improvement on existing therapies in patients with chronic pain conditions (e.g., Musculo-skeletal, neuropathic, and mixed pain conditions).

The following PICO was used to select literature to inform this review.

### Populations

The relevant population(s) of interest is individuals with chronic pain conditions (e.g., Musculo-skeletal, neuropathic, or mixed pain conditions).

### Interventions

The therapy being considered is non-immersive dry hydrotherapy. A session of dry hydrotherapy may be tailored to the individual in terms of temperature, intensity, localization, and duration, and is typically delivered in increments of 15 to 30 minutes. Regular sessions of at least once or twice a week have been recommended for full benefits. Dry hydrotherapy is typically delivered in a supine or seated position with bed (i.e., 'table') or chair (i.e., 'lounge') device models, respectively. For hydrotherapy bed models, patient position can be further manipulated to target treatment to affected sites.

### Comparators

The following interventions are currently being used to treat chronic pain conditions: physical therapy, pharmacotherapy, and other conservative therapies.

### Outcomes

The general outcomes of interest are symptoms (e.g., visual analog scale [VAS] for change in pain intensity), functional outcomes (e.g., range of motion), quality of life, medication use, and health resource utilization. Follow-up over months is of interest to monitor for outcomes in chronic pain conditions.

### Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies;
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought;
- Consistent with a 'best available evidence approach,' within each category of study design, studies with larger sample sizes and longer durations were sought;
- Studies with duplicative or overlapping populations were excluded.

### Review of Evidence

No peer-reviewed studies on the use of dry hydrotherapy in individuals with chronic pain conditions were identified.

### Health Technology Assessments

In 1998, the Washington State Department of Labor & Industries released a technology assessment on the AquaMED dry hydrotherapy unit distributed by JTL Enterprises.<sup>5</sup> Reviewers did not identify any peer-reviewed publications and summarized limited data reported on the original AquaMED website, including partial excerpts from a masters thesis from the University of West Florida psychology department, measurements from paraspinal scans from 10 patients before and after treatment, conclusions of ultrasound imaging of 20 patients before and after treatment, and results of thermographic imaging on 4 patients before and after therapy. The reviewers also noted that they could not identify any published research that supports claims

that dry hydrotherapy can take the place of multiple modalities (e.g., heat packs, wet hydrotherapy, massage and/or soft tissue manipulation) or that it provides any durable benefits.

Notably, JTL Enterprises, the parent company of both AquaMED and HydroMassage dry hydrotherapy units, announced a brand integration to market both devices under the HydroMassage brand in 2009.<sup>6</sup> In January 2020, the HydroMassage website listed a disclaimer stating that "all benefits of HydroMassage are temporary and apply only to the areas massaged. HydroMassage does not claim to cure or heal any conditions."<sup>7</sup> Manufacturer-provided clinical data previously shared on the AquaMED website is no longer available.

### **Section Summary: Dry Hydrotherapy for Chronic Pain Conditions**

No published, peer-reviewed literature was identified evaluating the use of dry hydrotherapy in individuals with chronic pain conditions. A technology assessment for the AquaMED device released from the Washington State Department of Labor & Industries in 1998 concluded that it could not identify any published research that supports claims that dry hydrotherapy can take the place of multiple modalities or that it provides any durable health benefits. Well-conducted studies comparing dry hydrotherapy to established interventions for chronic pain conditions are required to evaluate health outcomes.

### **Summary of Evidence**

For individuals with chronic pain conditions (e.g., musculoskeletal, neuropathic, and mixed pain conditions) who receive dry hydrotherapy, there are no published, peer-reviewed studies. Relevant outcomes are symptoms, functional outcomes, quality of life, medication use, and resource utilization. A health technology assessment released in 1998 for the AquaMED device also failed to identify published research to support claims that dry hydrotherapy can take the place of multiple modalities or that it provides any durable health benefits. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

### **Supplemental Information**

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the evidence review conclusions.

### **Practice Guidelines and Position Statements**

Guidelines or position statements will be considered for inclusion in 'Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

### **National Institute for Health and Care Excellence**

In 2017, the National Institute for Health and Care Excellence (NICE) published a guidance on the diagnosis and management of spondyloarthritis in individuals over 16 years of age.<sup>8</sup> The guidance recommends consideration of hydrotherapy as an adjunctive therapy to manage pain or improve function for individuals with axial spondyloarthritis. However, it is unclear whether this recommendation applies to the use of dry hydrotherapy.

### **U.S. Preventive Services Task Force Recommendations**

Not applicable.

### **Medicare National Coverage**

There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

**Ongoing and Unpublished Clinical Trials**

A search of [ClinicalTrials.gov](https://clinicaltrials.gov) in May 2022 did not identify any ongoing or unpublished trials that would likely influence this review.

**References**

1. Sidmar. Healthcare Data. 2022; <https://sidmar.com/healthcare/healthcare-data/>. Accessed May 20, 2022.
2. HydroMassage. Featured Products. 2022; <https://www.hydromassage.com/products/>. Accessed May 20, 2022.
3. Sidmar. Shop. 2022; <https://sidmar.com/shop/>. Accessed May 19, 2022.
4. SolaJet. The SolaJet. 2021; <https://www.solajet.com/products>. Accessed May 20, 2022.
5. Washington State Department of Labor & Industries. AquaMED Technology Assessment. 1998; [https://www.lni.wa.gov/patient-care/treating-patients/treatment-guidelines-and-resources/\\_docs/AquaMedTA.pdf](https://www.lni.wa.gov/patient-care/treating-patients/treatment-guidelines-and-resources/_docs/AquaMedTA.pdf). Accessed May 20, 2022.
6. Chiropractic Economics. AquaMED and HydroMassage announce brand integration. January 28, 2009; <https://www.chiroeco.com/aquamed-and-hydromassage-announce-brand-integration/>. Accessed May 20, 2022.
7. HydroMassage. HydroMassage Benefits: Ways Water Massage Can Improve Wellness & Recovery. January 20, 2022; <https://www.hydromassage.com/blog/hydromassage-benefits-for-wellness-recovery/>. Accessed May 19, 2022.
8. National Institute for Health and Care Excellence (NICE). NICE guideline [NG65]. Spondyloarthritis in over 16s: diagnosis and management. February 28, 2017; <https://www.nice.org.uk/guidance/ng65>. Accessed May 20, 2022.

**Documentation for Clinical Review**

- No records required

**Coding**

*This Policy relates only to the services or supplies described herein. Benefits may vary according to product design; therefore, contract language should be reviewed before applying the terms of the Policy.*

*The following codes are included below for informational purposes. Inclusion or exclusion of a code(s) does not constitute or imply member coverage or provider reimbursement policy. Policy Statements are intended to provide member coverage information and may include the use of some codes for clarity. The Policy Guidelines section may also provide additional information for how to interpret the Policy Statements and to provide coding guidance in some cases.*

Type	Code	Description
CPT®	97039	Unlisted modality (specify type and time if constant attendance)
HCPCS	None	

**Policy History**

This section provides a chronological history of the activities, updates and changes that have occurred with this Medical Policy.

Effective Date	Action
08/01/2022	New policy.

## Definitions of Decision Determinations

**Medically Necessary:** Services that are Medically Necessary include only those which have been established as safe and effective, are furnished under generally accepted professional standards to treat illness, injury or medical condition, and which, as determined by Blue Shield, are: (a) consistent with Blue Shield medical policy; (b) consistent with the symptoms or diagnosis; (c) not furnished primarily for the convenience of the patient, the attending Physician or other provider; (d) furnished at the most appropriate level which can be provided safely and effectively to the patient; and (e) not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of the Member's illness, injury, or disease.

**Investigational/Experimental:** A treatment, procedure, or drug is investigational when it has not been recognized as safe and effective for use in treating the particular condition in accordance with generally accepted professional medical standards. This includes services where approval by the federal or state governmental is required prior to use, but has not yet been granted.

**Split Evaluation:** Blue Shield of California/Blue Shield of California Life & Health Insurance Company (Blue Shield) policy review can result in a split evaluation, where a treatment, procedure, or drug will be considered to be investigational for certain indications or conditions, but will be deemed safe and effective for other indications or conditions, and therefore potentially medically necessary in those instances.

## Prior Authorization Requirements (as applicable to your plan)

Within five days before the actual date of service, the provider must confirm with Blue Shield that the member's health plan coverage is still in effect. Blue Shield reserves the right to revoke an authorization prior to services being rendered based on cancellation of the member's eligibility. Final determination of benefits will be made after review of the claim for limitations or exclusions.

Questions regarding the applicability of this policy should be directed to the Prior Authorization Department at (800) 541-6652, or the Transplant Case Management Department at (800) 637-2066 ext. 3507708 or visit the provider portal at [www.blueshieldca.com/provider](http://www.blueshieldca.com/provider).

*Disclaimer: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. Blue Shield of California may consider published peer-reviewed scientific literature, national guidelines, and local standards of practice in developing its medical policy. Federal and state law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over medical policy and must be considered first in determining covered services. Member contracts may differ in their benefits. Blue Shield reserves the right to review and update policies as appropriate.*

**Appendix A**

POLICY STATEMENT	
BEFORE	AFTER
<b>New Policy</b>  <b>Policy Statement:</b> N/A	<b>Dry Hydrotherapy for Chronic Pain Conditions 2.01.105</b>  <b>Policy Statement:</b> I. The use of dry hydrotherapy massagers for the treatment of chronic pain conditions is considered <b>investigational</b> .