

AquaMED Technology Assessment

Department of Labor and Industries

1. Background

AquaMED is being marketed as a dry hydrotherapy unit. The unit comes in two forms, a chair and a bed. AquaMED is distributed by JTL Enterprises, a company based out of Clearwater, Florida. JTL Enterprises is connected with two larger companies, Frexes International, which itself is a subsidiary of AJT & Associates, both of whom are engineering and design firms. The unit is listed as a physical medicine device, according to the coverage request received by the Department of Labor and Industries. AquaMed has 18 distributors in various states. The company lists over 180 owners, many of them chiropractic clinics. The company has four staff, but in 1997 contracted with Transworld, an international marketing firm, to develop markets in the Middle East and South America¹

Mechanics

The therapy consists of a patient laying or sitting in the AquaMED unit for 1-30 minutes. Both the chair and the bed contain interior jets surrounded by water enclosed in a plastic shell. The user stays dry. The jets are installed on a moving bar and rotate and pulsate while releasing streams of pressurized heated water along the user's body. In the bed, which visually resembles a waterbed, three jets mounted on a bar 12 inches below the user's body release the streams of water starting from the user's feet and moving back and forth along the body. The user controls the water pressure, speed and therapy area.

The AquaMed chair contains four jets, which focus on the lower lumbar region and move up to the neck. The user can adjust the water pressure.

Intended Effects

AquaMED is being marketed as a modality that increases blood circulation, which the manufacturer packet states will then lead to increased oxygen intake into the muscles, the benefits of which include lower blood pressure, increased range of motion, and increased endorphins which increase pain tolerance².

AquaMED intended benefits include reducing the need for other therapies, specifically massage, soft-tissue manipulation, hydrotherapy and heat. Their literature states that this modality combines these four modalities into one, thereby decreasing costs, equipment and time for the practitioner.

CPT Codes

The manufacturer supplies a list of 19 CPT codes that have been used to bill for this modality. Using various codes, this modality has been covered as any of the following:

¹ Barth. Cindy . 7/21/97. Orlando Business Journal

² AquaMed Manufacturer Packet

hot and cold packs, mechanical traction, whirlpool, constant baths, combination physiotherapy, massage, and various therapeutic and osteopathic procedures and manipulative treatment.

2. Regulatory Status

AquaMED has a 510k status from the FDA. The FDA lists this device as substantially similar to a device marketed pre-1976, which is listed in the coverage request as “AquaMassage”, by AMI. AquaMassage is a dry hydrotherapy unit marketed by Baron Stone Corporation. AquaMassage’s unit is a wraparound dry hydrotherapy device that visually resembles a CAT scan machine and works on the same principles of AquaMED.

3. Literature Review

A search of 22 peer-reviewed medical journals, including Physical Therapy and JAMA produced no clinical research and the following medical search engines: Dialog, Medline and HealthStar offered no articles on AquaMed or dry hydrotherapy. AquaMed refers readers to research in allied modalities that they say are all incorporated into AquaMED’s therapy. These include massage, hydrotherapy, soft-tissue manipulation and heat.

AquaMED’s *web site* contains four studies, including

1. partial excerpts from a masters thesis from the University of West Florida's psychology department³
2. measurements from PDT Paraspinal scans from 10 patients pre and post Aquamed therapy
3. Conclusions of ultrasound imaging of 20 patients pre and post treatment.
4. Results of thermographic imaging on 4 patients pre and post therapy

Aquamed's *coverage request packet* contained the complete master’s thesis noted above.

The masters thesis that comprises AquaMED’s “efficacy study” was sent to the Department as part of the coverage request package. The company concluded that AquaMED “*is an effective treatment modality for alleviating psychological stress, physical pain, and promoting wellness*”.

- Methods:

The complete study used 32 people, 16 **patients** randomly selected from a chronic pain clinic, 16 **non-patients** selected from the waiting room of the clinic. All participants received one thirty-minute treatment of AquaMED.

³ Burker. Valerie. Efficacy of Aquamed Therapy in Reducing Stress and Promoting Wellness in Chronic Pain Syndrome and Healthy Groups.

- Validity of measurements:

Psychological Stress: The indicator of “stress” was measured using six cardiovascular indices pre, during and immediately post treatment. The CV indicators included systolic and diastolic blood pressure, heart rate, stroke volume, cardiac output, and oxygen saturation.

Physical Pain: A questionnaire was used to measure subjective feelings of pain.

Promoting Wellness: No measurements included in study.

- Findings

Pain: Out of 16 CPS patients, 12 reported decreases in their perception of pain, averaging two points on a scale from one to ten. There is no data on the non-CPS patients’ perceptions of pain.

CV indicators: For CPS patients, statistically significant changes included decreases in diastolic blood pressure and heart rate ($r > .50$).

For non-CPS participants, cardiac output was the only significant change ($r > .52$).

Relaxation: 31 of 32 reported being relaxed immediately post therapy, data was not reported on pre-treatment feelings of relaxation.

A partial excerpt of the above study is posted on the company’s web site. The same chart showing results of CV indicators post-treatment was used in both, yet the composition and size of groups were different. In the partial study, 16 people participated, 8 were CPS sufferers. The same conclusions were stated.

There is no data in either the partial or complete study on long term benefits in the areas of psychological stress, physical pain and promotion of wellness.

Three other studies are posted on AquaMED’s web page. None of them gave information on procedures, methods or protocols. Only two have authors and only one has a date. None contained information on control groups or discussion on external and internal validity of the findings, or what was being measured.

1. The first had no information other than a chart showing scans of 15 patients pre and post treatment that stated all patients showed positive results.
2. The second study was conducted by Gary Weiss, MD, PA, who used ultrasound on 20 patients pre and post treatment to display soft-tissue injury. The only information included was a list of 7 diagnosis, a statement that the clinical presentations were consistent with patient’s complaints and his comments noting decreases in inflammation, fluid build-up and spasms. No information was presented on methodology and other factors.
3. The last study included 4 patients who underwent thermographic imaging pre and post treatment. This was done by Clarence Lloyd, MD on 9/22/90. His impression stated that the treatment causes significant differential in heat emission after treatment, which is greatest after two hours.

4. Economic Issues

Cost per treatment is \$20.00 according to manufacturers packet. A chiropractic clinic listed in the manufacturer packet was contacted and stated that 40.00 is the cost of an individual treatment.

5. Other health insurers positions

Workers Compensation

The manufacturer claims that several WC programs and private insurers have covered this modality. Of the WC physical therapy programs:

- New Mexico's liaison told me that it would be usually up to the provider's discretion because they have no rules limiting physical therapy. Rarely, the insurance company may decline the request.
- Minnesota, they have certain restrictions on ordering beds and passive types of treatment, so AquaMED therapy could be denied.
- Florida, the Workers Comp Bureau of Rehabilitation and Medical Services had never heard of it but stated that it probably would not come to their attention because the carriers make the determination of medical necessity.

Private Insurers

None of the private insurers listed as covering this treatment in the manufacturer packet had heard of AquaMED, though several would possibly pay for it if it were deemed therapeutic. AquaMED can be billed under many different CPT codes, making it difficult to track.

- Of the insurers listed as covering this device in the packet, two were contacted. QualMed's physical therapy consultants stated they have not heard of this device in any of the QualMed PT clinics⁴.
- Blue Cross of Washington normally would not cover AquaMED therapy as an authorized modality but would subject it to medical review, if requested, and possibly cover it⁵.

6. Medical profession's opinion

Though the manufacturers literature states that this device has been approved by the Washington State Chiropractic Association, Bob Mootz had never heard of it and stated that this type of endorsement only means that the modality is within the DC's scope of practice.

There is no literature on this product put out by the American Physical Therapy Association and the American Massage Therapy Association. The American Physical Therapy Association was contacted by phone, their research department had never heard of it.

⁴ NorthWest Physical Therapy Alliance

⁵ Blue Cross Medical Review representative

The University of North Texas Osteopathic Medical Clinic uses and endorses this modality and went on to state that they are “addicted to AquaMed”⁶.

The AquaMED packet contains 27 testimonials from a variety of medical professionals. The two reasons cited most frequently for use of AquaMED are: ease of compliance and increased income generated. Various other benefits noted including: increased patient relaxation, no set up or hands on therapy required, cost effective and sanitary, and eliminates need for hydrocollator packs. Specific medical benefits noted include: relaxes patients before manipulation, after nerve blocks, decreased muscle spasms, reduced chronic pain, improved circulation, sedative effect and general stress reducer.

Stan Gross, a D.C. in Missouri contacted, stated that the technology eliminated the need to hire and charge for massage therapists, is popular with clients and relaxes them before acupuncture and manipulation. He noted that it works well for myofascial pain syndrome by reducing congestion and tightness⁷.

7. Comparison with established technologies

As noted above, AquaMED intends their product to be used in lieu of heat packs, wet hydrotherapy, massage and/or soft tissue manipulation. There is no published research that support claims that this modality can take the place of multiple modalities or that this modality has any long-term benefit.

8. Additional Considerations

Product Relevance

This product is relevant to our patient population as it is geared towards injuries that include findings of chronic pain and decreased range of motion.

Input from other departments

The Department of Labor and Industries physical therapy consultant noted the lack of evidence that this modalities offers true benefits, which in a workers compensation environment means increased functional levels as evidenced by increased abilities and return to work. Also noted was the lack of evidence that AquaMED therapy produces the same results as the four therapies the company states it substitutes for. In chronic pain, this therapy may be considered palliative, rather than curative because of the lack of research on long-term benefits. If considering coverage of AquaMED therapy the consultant recommends the following issues be considered:

- Treatment must require preauthorization to avoid treating palliatively
- AquaMED should not be used exclusively
- Must be combined with active therapy, including strengthening and conditioning.
- It should be considered on case by case basis
- The CPT code issues may make this difficult to track.

⁶ University of North Texas Osteopathic Clinic

⁷ Stan Gross, DC. 10/26/97

Prevalence/degree to which the technology is currently being used

The product is currently being marketed on the Internet to the general public and to medical providers, their packet contains a “sample letter of medical necessity” and many suggested CPT codes to use for billing.

AquaMED is being marketed via the trade show route and has shown or is being shown at the following shows in 1998: American Physical Therapy Show, Texas and Washington Chiropractic Shows, Florida Intl. Med. Expo, Health Industry Distributors Show, AAPM, American Academy of Physical Medicine and Rehab and MedTrade.