**Aqua Relief System Uses**
The Aqua Relief System treats:
- Post-Op for people recovering from surgery or accident.
- Chronic pain for people with arthritis, carpel tunnel syndrome, etc.
- Poor circulation for people who have neuropathy, diabetes, edema, etc.

**Unique Treatment System**
The Aqua Relief System includes the following unique features:

- **Single or Dual Foot Bladder** - Similar to a slipper or boot that completely encompasses the patient’s foot and ankle like a boot, providing therapy for the entire foot and ankle.

- **Universal Bladders** - Specially designed to provide treatment to virtually any part the body.
  - Knee
  - Back
  - Shoulder
  - Elbow
  - Wrist
  - Neck

- Single Foot w/ sock
- Double Foot w/ socks
- Small Universal w/ Belt
- Large Universal 13 x 24” w/ Belt
Aqua Relief – Water circulating Heat Pad with Pump

A water circulating heat pad with pump – this modality provides localized heat therapy that is safe and effective (HCPCS E0217). Adjustable temperature from 30F to 120F (107F fixed for sensitive skin on low heat setting) providing controlled heat (water) within safe limits that relaxes muscles, increases blood flow and reduces edema as well as pain. Patented therapy pads are used for treatment.

The water circulating heat pad with pump provides a therapeutic benefit that is not achieved solely by using a standard electric heat pad, such as increased safety, delivery of a specific temperature, and contour to treatment site. The Aqua Relief system is clinically therapeutic for those patients who are susceptible to burns, i.e. Diabetics Neuropathy patients.

The Aqua Relief® System is a clinical therapeutic pain management and circulatory improvement system that can be used in the home. It’s an all-in-one system that combines heat therapy and cold therapy, allowing treatment for an injury, as well as help improve blood circulation and reduce the discomforts associated with Diabetes.

Diabetics are prone to circulatory problems in their extremities feet. The Aqua Relief® System delivers pain relief to achy feet, and other areas due to diabetic neuropathy, arthritic pain, or carpal tunnel syndrome. It is a versatile hot/cold relief therapy that will help both systemic pain conditions as well as specific pain conditions; (knee, back, wrist, and shoulder….etc).

The Aqua Relief System uses simple tap water and heats up to the desired temperature.

- Covered by Medicare and many private insurances
- Bladders for the foot (single & double)
- Bladders for entire body; knee, back, wrist, shoulder, etc…(sm. or lg. Universal)
Aqua Relief System Benefits:

- The Aqua Relief System uses continuous thermal therapy to minimize tissue damage and scarring, helps reduce pain and discomfort, and helps reduce dependency on pain medication.
- The Aqua Relief System® uses heat 107°F — 120°F water to help improve blood circulation in the feet, and other areas of the body.
- Cold water can also be used to reduce swelling that is associated with Diabetic Neuropathy, Edema, Arthritis, and Surgery.
- Long lasting heat / cold therapy due to extra insulation.
- Versatile Universal bladder allows for treatment of any body part.
- Foot Bladder(s) allow for treatment of circulatory and pain problems in the feet.
- System uses regular tap water.

This product covers a variety of conditions which could benefit a variety of patients.

Some, but not all of the of the diagnosis's include:

- 714.00 Rheumatoid Arthritis
- 715.90 Osteoarthritis NOS-Unspec
- 721.30 Lumbosacral Spondylosis
- 724.30 Sciatica
- 459.80 Poor Circulation
- 714.89 Inflamm Polyarthrop-NEC
- 728.85 Muscle Spasm
- 721.90 Spondylosis NOS w/o Myelop
- 782.30 Edema

ICD9 needed: Chronic pain ☐  Inflammation ☐  Neuropathy ☐  Traumatized Tissue ☐

Other diagnosis: ____________________________________________________________

Therapeutic use is for: ____________________________________________________________

(ex. Increased circulation, reduction of pain or inflammation, increased mobility etc)

Qualified Patients may receive

- 1 Therapy Pump (Once every 5 years) +
- 1 Bladder (Replaceable as needed if unusable)

**NOTE:** Patient will NOT qualify if Medicare paid for a heating pad in the last five years.
Aqua Relief® System - Hot Therapy  - What exactly does heat do?

- Improves circulation
- Improves cell function (metabolism)
- Decreases stiffness in tendons and ligaments
- Relaxes the muscles and decreases muscle spasm
- Lessens pain

Heat therapy is effective in the dilation of blood vessels, thereby increasing the blood flow to the heated area. Heat therapy has a variety of uses, the most common being treatment of aches and pains in joints and muscles.

The Aqua Relief® System circulates moist heat therapy to the affected body part at any desired temperature between 107 °F and 120 °F.

Continuous moist heat therapy helps minimize tissue damage and scarring, helps reduce pain, discomfort, and helps to reduce dependency on pain medication.

NOTE: Medicare ONLY reimburses for Heat Therapy

Added Benefit of Cold Therapy  - What exactly does cold do?

- Promotes healing
- Prevents discomfort in muscle and joints
- Reduces swelling and pain

Areas of the Body that can benefit from the Aqua Relief System

- **Patented foot bladder(s)** allows for treatment of circulatory and pain problems for one (single bladder) or both (double bladder) feet. Foot bladder comes with a sock for feet.

- **Universal and 13x24” bladder(s)** allows for treatment of any body part; ankle, knee, hip, back, hand, wrist, elbow, shoulder, chest, breast, neck, and other problematic areas. A Velcro belt for easy body attachment is provided with either sm. or lg. Universal bladder.
February 15, 2006

Mr. Steven Drazen, Director of Distribution
Dr. Zen Inc.
156 Harston Court
Heathrow, FL 32746

Dear Mr. Drazen:

This letter is in response to your request received in our office on February 14, 2006 for HCPCS coding assistance. Coding assistance provided by the SADMERC is reflective of the four Medicare Durable Medical Equipment Regional Carriers (DMERCs). Following is/are the proper HCPCS codes to bill the four DMERCs:

**Aqua-T Pump, manufactured by Dr. Zen Inc.**
E0217 Water circulating heat pad with pump

**Aqua Therapy Pad, manufactured by Dr. Zen Inc.**
E0249 Pad for water circulating heat unit

The assignment of a HCPCS code to the product(s) should in no way be construed as an approval or endorsement of the product(s) by the SADMERC, DMERCs, or Medicare, nor does it imply or guarantee claim reimbursement.

Please refer to your DMERC Supplier Manual for claim submission instructions such as applicable HCPCS modifiers and required documentation. If you have questions regarding claim submission, reimbursement or coverage, contact your regional DMERC.

Should you need further HCPCS coding assistance, please contact us at the address below, at our web site (www.palmettogba.com) or by calling our Helpline at (877) 735-1326. The Helpline hours of operation are Monday through Friday from 9 a.m. to 4 p.m. EST, with extended hours on Wednesday from 4 p.m. to 6 p.m. EST.

Yours Truly,

[Signature]

Andrela Riley
HCPCS Representative

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Palmetto GBA
Statistical Analysis Durable Medical Equipment Regional Carrier
Post Office Box 100148 • Columbia, South Carolina • 29202-3143
A CMS Contracted Intermediary and Carrier
Statement of Medical Necessity for
Water Circulating Heat Pad with Pump

Patient Name_________________________________________________________________________

Address______________________________________________________________________________

Date of Birth __________________  Male □  Female □  Medicare # ___________________________

I hereby certify that the following equipment is medically necessary as part of the patient's treatment program. I certify that the following statement(s) are true.

The water circulating heat pad with pump provides a therapeutic benefit that is not achieved solely by using a standard electric heat pad, such as increased safety, delivery of a specific temperature, and contour to treatment site. Specifically therapeutic for those who are susceptible to burns, i.e. diabetics.

**Patient requires:** A water circulating heat pad with pump – this modality provides localized heat therapy that is safe and effective (HCPCS E0217). Adjustable temperature from 30°F to 120°F (105°F fixed for sensitive skin on low heat setting) providing controlled heat (water) within safe limits that relaxes muscles, increases blood flow and reduces edema as well as pain. Patented therapy bladder(s) are used for treatment (HCPCS E0249).

**Please specify body part(s) needing therapy** _____________________________________________

**Diagnosis:** ☑ Please check all that apply

- □ 714.00 Rheumatoid Arthritis
- □ 714.89 Inflamm Polyarthrop-NEC
- □ 715.90 Osteoarthrosis NOS-Unspec
- □ 728.85 Muscle Spasm
- □ 721.30 Lumbosacral Spondylosis
- □ 721.90 Spondylosis NOS w/o Myelop
- □ 724.30 Sciatica
- □ 782.30 Edema
- □ 459.80 Poor Circulation

ICD9 needed:
- Chronic pain _______ Inflammation _______ Neuropathy _______ Traumatized Tissue _______
- Other diagnosis: ______________________________________________________________________

**Therapeutic use is for:** _____________________________________________________________

(ex. Increased circulation, reduction of pain or inflammation, increased mobility etc)

**Estimated Length of need (# of months):** _______ 1- 99  (99=lifetime)

- Usage:________________________ Hours:________________________ Per day ____________________ or Continuous _______

(Check skin every 20 minutes for possible adverse reactions.)

What other treatments have been tried? ____________________________________________________

Physician agrees to keep chart notes on file as they pertain to this product.

<table>
<thead>
<tr>
<th>Physician Name</th>
<th>NPI#</th>
</tr>
</thead>
<tbody>
<tr>
<td>Address</td>
<td>City</td>
</tr>
<tr>
<td>Office Phone</td>
<td>Office Fax</td>
</tr>
</tbody>
</table>

*Attending Physician Signature (Original Signature Only – No Stamps) Date*
Re: Water Circulating Heat Pad with Pump

Dear Dr.

Our patient in-take form has indicated that your patient has the conditions(s) listed on the enclosed form and may qualify for the Water Circulating Heat Pad with Pump – Aqua Relief Therapy System under the Medicare guidelines.

It is well known that diabetics are prone to poor circulation in their lower extremities, legs and feet. Patients often experience, inflammation, edema, and neuropathy as well. The water circulating heat pad with pump delivers warm water to their feet through the use of a patented anatomically shaped pad that covers the entire foot. This modality provides localized heat therapy that is safe and effective. Adjustable water temperature from 30F to 120F (low heat setting fixed at 105 F for sensitive skin) providing controlled heat (water) within safe limits that relaxes muscles, increases blood flow and reduces edema as well as pain.

The water circulating heat pad with pump can be beneficial for other non-diabetic patients who suffer from Rheumatoid Arthritis, Muscle Spasms, Sciatic, Edema, Inflammation, Traumatized Tissue, Chronic pain and other poor circulation conditions. Through the use of the Universal pad, all areas of the body can receive therapy. The pad is uniquely shaped allowing for use in flat areas such as the back, as well as wrapped around the arm, leg, neck, or any other area that is needed.

Please review and complete that attached Statement of Medical Necessity for Water Circulating Heat Pad with Pump, Aqua Relief Therapy System. If you have any questions concerning the patient or the product, please do not hesitate to call.

Thank you for your attention to this matter.

Sincerely,
Patient Evaluation Aqua Relief System

**Patient**
Name________________________________________________________ DOB ___________________
Address:_____________________________________________________ Male □ Female □
City:__________________________State:_______ Zip: ____________ Phone_____________________

**Physician**
MD or DO Name: Dr. __________________________________________ NPI No. ____________

**General Patient Profile**
Walks: Independently□ Uses Cane□Uses Walker□ Uses Wheel Chair□ Weight (lbs.) _____ Height____

**Medical Necessity**
Please specify body part(s) needing therapy ________________________________

**Diagnosis:** □ Please check all that apply
□714.00 Rheumatoid Arthritis □714.89 Inflamm Polyarthrop-NEC
□715.90 Osteoarthritis NOS-Unspec □728.85 Muscle Spasm
□721.30 Lumbosacral Spondylosis □721.90 Spondylosis NOS w/o Myelop
□724.30 Sciatica □782.30 Edema
□459.80 Poor Circulation

ICD9 needed: Chronic pain _____ Inflammation _____ Neuropathy _____ Traumatized Tissue ___

Other diagnosis: ___________________________________________________________

Therapeutic use is for: ______________________________________________________
(ex. Increased circulation, reduction of pain or inflammation, increased mobility etc)

**Order**
Aqua Relief Pump with bladder □ Single Foot □ Double Foot □ Universal w/ Belt

Fitter Name ______________________________________________________ Date ___________________
Aqua Relief System Delivery & Warranty

Product Use & Doctor Instructions

Body part(s) needing therapy _______________________________________________
Estimated Length of need (# of months): _______ 1- 99  (99=lifetime)
Usage:________________  Hours:_____________ Per day _____________
or ___  Continuous when needed by patient.

IMPORTANT: Check skin every 20 minutes for possible adverse reactions.

Product Instruction & Delivery Acknowledgement

I acknowledge receiving instructions in the proper use and care of the Aqua-Relief Therapy Pump. I have had my financial responsibilities explained.

I have received the Aqua-Relief Therapy Pump, in good condition and am satisfied with the product(s).

Return Policy & Equipment Warranty

Return sales will be accepted within 14 days from the date merchandise is received and refunds will be issued for such merchandise. Items must be returned in re-salable condition, in the original boxes. Dirty or used-looking items will not be accepted. Returns after 14 days and Custom Order Items are subject to fees.

The Aqua Relief System Therapy Pump carries a one year limited manufacturer’s warranty. Provider will repair or replace, Medicare-covered equipment that has defected parts. Provider will notify all Medicare beneficiaries of the warranty coverage, and we will honor all warranties under applicable law.

I have read, and acknowledged the above information.

I, ________________________________________________ Date: __________________
(PATIENT SIGNATURE)