

PLAIN LANGUAGE SUMMARY

Calmare[®] Pain Therapy Treatment

Utilization Management Policy # 485

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What is Calmare therapy and what is known about it so far?

Calmare (also known as Scrambler) therapy is a non-invasive pain therapy device for the management of severe chronic and acute pain. It is used when more common treatments such as medication are ineffective. Patients are connected to the Calmare Pain Therapy Treatment device by small electrodes (similar to those used in EKG and other medical procedures) that are placed on the skin near the area where there is pain. The device sends a very low current of electrical stimulation through the nerve fibers attempting to block pain signals to the brain.

The uses of this therapy for nerve pain caused by disorders that are not due to cancer (noncancer-related) such as sciatica, low back pain, post-surgical pain, etc. are largely based on very low quality clinical research. There is a need for higher quality information in order to make confident judgments about benefits and risks.

How was Calmare therapy evaluated?

A work group of clinicians was assigned to review the available research. The internet was searched for articles about Calmare (Scrambler) therapy. The work group independently examined the selected research studies. A broadly accepted rating scale was used. Possible ratings were high, moderate, low, or very low quality. Additionally, the positions and guidelines of other professional and healthcare groups were evaluated.

Before it was approved, the policy was presented to a series of committees that included independent health care practitioners.

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What did the work group find?

There is only limited research about the effectiveness of Calmare therapy for the treatment of nerve pain due to noncancer-related disorders. The overall research quality was rated as *low*. Better quality studies are needed.

It was not possible to make a determination that Calmare therapy provided more benefit, when compared to generally recommended treatments for pain management.

What were the limitations of the information?

Each of the studies involved several small groups of people. It is uncertain that the results apply to most people with similar disorders.

The use of Calmare therapy for many for the treatment of nerve pain due to noncancer-related disorders such as neck pain has not been studied.

What are the conclusions?

Calmare (Scrambler) therapy is viewed as *unproven and not medically necessary* for the treatment of noncancer-related nerve pain. Further research is needed before its use can be considered an established treatment option for any spinal condition.