

Health Technology Assessment Brief: Brevio Nerve Conduction System

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Office of the Medical Director

Background

The NeuMed Brevio is a handheld device intended for use in evaluating nerve function. Similar to conventional nerve conduction study devices, the Brevio assesses function via surface electrodes. According to the NeuMed¹ website (manufacturer of the Brevio), the Brevio is a 4th generation product following the Nervepace. Clinical studies of the diagnostic value and accuracy of the Nervepace are cited as support of the diagnostic utility of the Brevio.

FDA Status

The Brevio is approved by the Food and Drug Administration through 510(k) (K012069). It is a Class II device and is classified as a Nerve Conduction Velocity Measurement Device.

Brevio is a product of Neurotron Medical, Inc. The predicate devices for the Brevio are 2 similar units from Neurotron called the Nervepace (VS-200) and the Digital Electroneurometer (S-100). Summary FDA information indicates the Brevio “has the same technological characteristics as the predicate devices.” Additionally, changes to software allow the device to “pick out the latency and amplitude of waveforms presented to determine the values associated with them.”

Literature Search

A search for relevant scientific papers addressing the diagnostic validity and reliability of testing with the Brevio device was completed. This included searching PubMed using the terms ‘brevio’, ‘neurotron’ and ‘nerve conduction’. Papers were identified through the Neumed.com manufacturer web pages.

Results of this search failed to identify studies addressing the diagnostic capabilities of the Brevio. Clinical research papers listed in support of Brevio, as available on the Neumed.com web pages, include studies performed using the Nervepace device. A literature review completed by the American Academy of Neuroelectrodiagnostic Medicine (AANEM) is included as well as one study published since the AANEM review. The AANEM reviews critically evaluate the relevant papers cited on the Neumed web pages.

Evidence Review

The AANEM published a literature review of the Nervepace Digital Electroneurometer in Carpal Tunnel Syndrome in 2003¹. This report updated the association’s original review from 1999. The authors of this review concluded that the Digital Electroneurometer and the Nervepace devices are experimental. They recommended further research would be required to 1) establish

¹ NeuMed Inc. and Brevio are registered trademarks of Neurotron Medical, Inc.

reference values, 2) determine the reliability and repeatability, and 3) the sensitivity and specificity when used to diagnose carpal tunnel syndrome.

Tanaka et al (2005)² published results from a prospective study of the accuracy of the Nervepace in assessing distal motor latency (DML) of the median nerve. The authors compared DML results among patients with and without carpal tunnel syndrome (CTS). Nervepace DML was compared to measures completed with a traditional EMG system (Dantec). The authors found good correlation between results of DML measures in 15 normal patients. However, in patients with CTS, Nervepace was not able to acquire a DML in a number of limbs measurable with the Dantec, and DML correlation dropped dramatically above 6.0 ms. The authors' conclusions include that the accuracy and reliability of Nervepace became unacceptable at DML values above 6.0 ms. The authors further concluded that, though there may be a role for portable EMG systems like the Nervepace, this device may be too limited in its ability to capture sensory data.

Other Insurers

Aetna considers the Brevio to be experimental and investigational³.

Regence considers automated nerve conduction studies investigational. This policy does not specifically address Brevio or handheld devices.

Noridian Administrative Services, LLC (Medicare contractor for region including Washington) does not reimburse for NCS using handheld devices, which are incapable of wave-form analysis. Use of these is included in evaluation and maintenance service⁴.

Conclusion

At this time there appears to be no evidence addressing the diagnostic accuracy of the Brevio nerve conduction system. There is adequate evidence available to evaluate the predicate and predecessor device to the Brevio, the Nervepace. This evidence does not support the accuracy or reliability of Nervepace for use as a diagnostic or screening tool for any condition(s) and specifically for carpal tunnel syndrome.

References

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2. Tanaka H, Hashizume H, McCown C, Senda M, Nishida K, Inoue H. Accuracy of a portable electroneurometer for measuring distal motor latency. *J Orthop Sci*. Sep 2005;10(5):445-450.
3. Aetna. Clinical Policy Bulletin: Nerve Conduction Velocity Studies. *Number: 0502*. 2007.
4. Noridian Administrative Services LLC. LCD for Nerve Conduction Studies and Electromyography. *L14911* [Accessed May 23, 2007].