

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

ZERO CROSSERS



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EXECUTIVE SUMMARY

PURPOSE

This report quantifies Medicare reimbursement for in-office diagnostic tests of arteries and veins conducted with ultrasonic detecting devices using a "zero-crossing" technique.

BACKGROUND

In a previous report (Low-Cost Ultrasound Equipment, OEI-03-88-01401), we reviewed the appropriateness of Medicare reimbursement for diagnostic tests conducted with unsophisticated, ultrasonic devices. We encountered two basic types of devices--Pocket Dopplers and Zero Crossers.

Pocket Dopplers are the least sophisticated type of ultrasound equipment. Small, hand-held devices, they are typically nondirectional and their only output is audio.

A variety of devices exist at a technological step above Pocket Dopplers. These devices--which we term Zero Crossers--document test results via a recordable waveform, similar to an electrocardiograph (EKG) record. Typically, these devices are bidirectional, constructed in a table-top configuration, and cost between \$3000 and \$7000.

METHODOLOGY

This report is based on a random sample consisting of 480 services from 8 Medicare carriers. The selected carriers represent more than half of in-office allowances for ultrasonic vascular tests nationally. We limited the selected services to in-office diagnostic vascular tests conducted during 1988.

FINDINGS

Seventeen Percent of Services Were Conducted With Zero Crossers

Fifty-three services in our sample--representing 17 percent of the responses--were conducted with Zero Crossers. We calculate that Zero Crossers were used to conduct 62,079 services in 1988.

Medicare Allowed Between \$8 and \$12 Million for Services Conducted With Zero Crossers in 1988

We estimate that Medicare allowed about \$8 million for services conducted with Zero Crossers. If non-respondents and respondents had the same usage rate, an additional \$4 million could have been allowed for Zero Crossers in 1988.

Many Tests Done With Zero Crossers May Be Inaccurate

A review of scientific literature revealed a number of studies highlighting deficiencies in the accuracy of equipment using zero-crossing technology.

Reimbursements for Zero Crossers and More Sophisticated Equipment are Similar

Zero Crossers were reimbursed about the same as devices producing sophisticated and clinically detailed imaging. The Medicare allowance for Zero Crossers was approximately \$125 (weighted average) while the average allowance for state-of-the-art equipment was about \$135.

CONCLUSION

Our "Low-Cost Ultrasound Equipment" report recommends that HCFA advocate revisions in procedure codes and reimbursement rates to reflect the different levels of sophistication and quality of diagnostic information provided in such tests.

We continue to support this recommendation. If HCFA adopts it, potential savings from the 5-year period beginning 1992 range from about \$25 million to \$124 million depending on the reimbursement level.

TABLE OF CONTENTS

EXECUTIVE SUMMARY

INTRODUCTION 1

FINDINGS 5

CONCLUSION 7

APPENDIX A-1

INTRODUCTION

PURPOSE

This report quantifies Medicare reimbursement for in-office diagnostic tests of arteries and veins conducted with ultrasonic detecting devices using a "zero-crossing" technique.

BACKGROUND

Diagnosticicians use sensitive instruments operating on ultrasound principles to detect arterial and vascular diseases. These devices emit high frequency soundwaves into the tissues. Depending on the sophistication of the device used, reflected ultrasound signals may be detected by one of four techniques--audio only, strip-chart recording using a "zero crossing" technique, spectral analysis, or imaging. In general, audio-only devices are considered the least accurate and refined of the various methods. Imaging devices produce superior diagnostic output.

Diagnostic ultrasound tests are usually conducted using "mid-level" equipment. This equipment costs from \$15,000 to \$60,000 and offers a wide range of sophisticated options, such as remote control, selectable frequency ranges, and video spectrum analysis of blood flow measurements. The ensuing diagnostic output provides a level of quality which meets the needs of most clinicians.

More expensive (so-called "state-of-the-art") equipment offers two-dimensional displays, computerized analysis, and color-flow imaging. Devices equipped with color-flow imaging produce video pictures of blood flow velocities in combinations of red, blue, and green. Changes in the intensity of color and blood flow velocity can indicate an irregularity, such as a blockage.

Nationally, Medicare allowances for four major procedure codes used in diagnostic ultrasound tests of arteries and veins surpassed \$88 million for in-office services in 1989, an increase of more than 31 percent over 1988. These tests increased almost 25 percent for the corresponding period.

In a previous report (Low-Cost Ultrasound Equipment, OEI-03-88-01401), we reviewed the appropriateness of Medicare reimbursements for diagnostic tests conducted with inexpensive, relatively unsophisticated ultrasonic devices. We encountered two basic types of devices--Pocket Dopplers and Zero Crossers.

Pocket Dopplers and Zero Crossers

Pocket Dopplers are the least sophisticated type of ultrasound equipment. A hand-held device, the typical Pocket Doppler transmits a continuous or pulsed beam of ultrasound at moving blood cells. Typically, the Pocket Doppler is nondirectional (i.e., it is incapable of determining the direction of blood flow) and produces audio signals only. Such tests can be conducted in less than five minutes. These devices are marketed as diagnostic ultrasound equipment and generally cost under \$1000.

We reported the impact of Pocket Doppler usage in a Management Advisory Report, entitled "Pocket Dopplers" (OEI-03-91-00461). Our findings on Zero Crossers are addressed in this report.

A variety of devices exist at a technological step above Pocket Dopplers. These devices--which we term Zero Crossers--document test results via a recordable waveform. This process converts the mean frequency of the doppler signal into a proportional display via a frequency-to-voltage (zero crossing) strip-chart tracing, similar to an electrocardiograph (EKG) recording. Typically, these devices are bidirectional (capable of determining blood flow direction), constructed in a table-top configuration, and cost between \$3000 and \$7000.

Test result evidence is the most obvious clinical difference between Pocket Dopplers and Zero Crossers. (Pocket Dopplers do not produce objective test evidence while Zero Crossers provide tangible evidence.) More sophisticated equipment provides detailed documentation using spectral analysis or high-resolution images.

A device using zero-crossing technology records the average speed of all the cars on a highway, while spectral analysis registers the individual speed of each car, according to an analogy offered by one expert. In effect, a Zero Crosser provides a single frequency display of the soundwave whereas spectral analysis records multiple quantitative frequencies. State-of-the-art equipment typically produces test results in a video hard-copy image.

Approximately 15 manufacturers produce and market Pocket Dopplers and Zero Crossers. Industry sources estimate that at least 100,000 units are in active use in the medical community. About 20,000 new units were sold in 1990.

Previous Inspection Findings

Our previous study highlighted a number of issues and concerns. Briefly, we found:

- ▶ A variety of ultrasound equipment exists ranging from Pocket Dopplers to state-of-the art equipment costing more than \$300,000.
- ▶ Medicare procedure codes fail to distinguish between test types or results. The Health Care Financing Administration Procedure Coding System (HCPCS) does not differentiate between the extent of a test or the nature of test results. Further, the same rate of reimbursement applies to a test without regard to its extensiveness or the quality of the data produced.
- ▶ There are strong incentives for excessive use. Since Medicare reimbursements do not consider the quality of equipment used and the quality of test results, excessive payments can be claimed for a relatively simple screening test based on a comparatively modest investment.
- ▶ The Health Care Financing Administration (HCFA) is vulnerable to inappropriate billings. Medicare carriers lack sufficient safeguards to detect billings based on inferior test results.
- ▶ A precedent exists to deny payments for Pocket Doppler tests. In a previous decision, HCFA ruled that a portable hand-held x-ray instrument "should be reimbursed as part of the physician's professional service, and no additional charge should be allowed."

We recommended that HCFA prohibit payment for Pocket Doppler tests and advocate revisions in procedure codes and reimbursement rates to reflect the different levels of sophistication and quality of diagnostic information provided in ultrasound tests.

METHODOLOGY

This report is based on a 2-stage random sample consisting of 480 services from 8 Medicare carriers. During the first stage of sampling, 8 Medicare carriers were randomly selected, with the probability of selection proportionate to total amounts reimbursed under Medicare in 1988. The selected carriers represent more than half of in-office allowances for ultrasonic vascular tests nationally. The carriers were Florida Blue Shield; Michigan Blue Shield; Empire Blue Shield (New York); California Blue Shield; Arkansas Blue Shield, as the carrier for Louisiana; Blue Shield of Indiana; Transamerica Occidental of California; and the Railroad Retirement Board.

At the second stage of sampling, we selected 60 services per carrier from 1988 Part B Medicare Annual Data (BMAD) billings. We limited the selected services to in-office diagnostic vascular tests conducted during 1988. The services consist of four of the most commonly used HCPCS codes by practitioners of these tests: 93910 (noninvasive studies of lower extremity arteries); 93950 (noninvasive studies of lower extremity veins); 93860 (noninvasive studies of carotid arteries); and 93890 (noninvasive studies of upper extremity arteries).

After the carriers supplied us with pertinent claims data, we wrote to the practitioners requesting detailed information on the types of equipment used to conduct the tests. In particular, we were interested in five features--configuration (pocket, portable, pen, tabletop); power source; blood flow direction; price; and documentation capability. We also requested copies of any charts, graphs, or printouts produced during the tests.

We reviewed the responses against scientific publications, manufacturers' catalogs, and related technical materials to determine if low-cost devices had been used to conduct the tests. We consulted with a Registered Vascular Technologist (RVT) who reviewed test results and assisted us in making determinations.

FINDINGS

Seventeen Percent of Services Were Conducted With Zero Crossers

Sixty-five percent of the providers in our sample (314 of 480) responded to our requests. Based on our analysis, we determined that 53 services in our sample--representing 17 percent of the responses--were conducted with Zero Crossers. Applying the 17 percent usage rate and the 65 percent response rate, we calculate Zero Crossers were used to conduct 62,079 services in 1988. If non-respondents' usage rates were the same as for respondents, services conducted by Zero Crossers could increase by 33,427 in 1988, bringing total 1988 services to 95,506.

In our "Pocket Doppler" report, we found that Pocket Dopplers accounted for 7 percent of ultrasound tests in 1988. Taken together, tests done by Pocket Dopplers and Zero Crossers represent nearly one-quarter of all in-office ultrasound tests conducted in 1988.

Medicare Allowed Between \$8 and \$12 Million for Services Conducted With Zero Crossers in 1988. Allowances for 5 Years Could be \$124 Million

Allowances for sample services conducted with Zero Crossers ranged from a low of \$15 to a high of \$324 with an overall weighted average of \$125. Based on our projections, we estimate that Medicare allowed approximately \$8 million for these services. If we assume that non-respondents and respondents had the same usage rate, an additional \$4 million could have been allowed for Zero Crossers in 1988.

We estimate that Medicare will allow approximately \$124 million for services conducted with Zero Crossers for the 5-year period beginning in 1992. To estimate Medicare allowances, we applied the 65 percent response rate and the 17 percent Zero Crosser usage rate to the 700,700 allowed services for the 4 codes in 1989. Non-respondents were not included in our calculations even though there is no reason to suspect the usage rate for non-respondents differs from respondents. We assumed an annual 20 percent increase in the number of services (the actual annual increase from 1987 to 1989 was between 25 and 30 percent). We used the 1988 average allowed amount of \$125 per service for all 5 years. We omitted possible reimbursement increases because of recent legislative changes designed to minimize increases.

Many Tests Done With Zero Crossers May Be Inaccurate

Deficiencies in the accuracy of equipment using zero-crossing applications have been recognized for many years. A 1988 study of 157 patients concluded:

"...the errors...of zero-crossing techniques have been recognized for 10 to 15 years...The inability of the zero-crossing tracing to provide complete and accurate information in 50 percent of the cases severely limits its usefulness."¹

A 1977 study on multiple arterial readings concluded:

"...recordings made by zero-crossing detectors cannot be used for quantitative analysis. Moreover, errors are common enough that even qualitative interpretation of the recordings may be questionable in many cases."²

Additional pertinent references are cited in the Appendix.

Our consultant who examined a sample of test results confirmed that Zero Crossers often produce questionable results compared with more sophisticated equipment.

Reimbursements for Zero Crossers and More Sophisticated Equipment are Similar

The 53 devices we determined to be Zero Crossers were reimbursed about the same as devices producing sophisticated and clinically detailed imaging. Overall, the weighted Medicare average allowance for Zero Crossers was approximately \$125 while the average allowance for services conducted with more sophisticated equipment was \$135.

In their efforts to market Zero Crossers, manufacturers do not neglect the potential compensation which their products provide. As an example, one of the brochures we encountered contained this advice:

In addition to its diagnostic value, low cost and simplicity of operation, the annotated charts provide invaluable documentation in this age of medical-legal liability. (Name of device) tests are MEDICARE approved and reimbursable by third party insurers under several CPT codes. Average reimbursement exceeds \$150.

¹ Cynthia Kupper Burnham, RVT, Nancy Dewhirst, RVT, and Steven J. Burnham, MD, "Doppler Spectral Waveforms For Recording Peripheral Arterial Signals: The Preferred Method," *The Journal of Vascular Technology*, April, 1989.

² K. Wayne Johnston, MD, Bruno C. Maruzzo, MAsc, and Richard S. C. Cobbald, ARCS, MSc, PhD, "Inaccuracies Of A Zero-Crossing Detector For Recording Doppler Signals," *Surgical Forum*, 1977.

CONCLUSION

Our report on Low-Cost Ultrasound Equipment recommends that HCFA advocate revisions in procedure codes and reimbursement rates to reflect the different levels of sophistication and quality of diagnostic information provided in such tests. (We understand HCFA has encouraged procedure code revisions in vascular tests during recent contacts with the American Medical Association's editorial board.)

We estimate the following potential savings on Zero Crosser services if HCFA adopted our recommendation. The chart depicts various payment options ranging from non-coverage to \$100 for 1-year and 5-year periods.

ZERO CROSSERS

REIMBURSEMENT	1-YEAR SAVINGS	5-YEAR SAVINGS
\$0	\$16.7 MILLION	\$124.5 MILLION
\$20	\$14.0 MILLION	\$104.5 MILLION
\$40	\$11.4 MILLION	\$84.6 MILLION
\$60	\$8.7 MILLION	\$64.7 MILLION
\$80	\$6.0 MILLION	\$44.8 MILLION
\$100	\$3.3 MILLION	\$24.9 MILLION

APPENDIX

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