

Subject:	PCA3 medical test as diagnostic intervention for prostate cancer
Summary	<p>CVZ has examined whether using the PCA3 gene expression test on patients with suspected prostate cancer and a negative initial series of biopsies as a triage test is effective (clinical utility) for decision-making on whether to carry out a second series of biopsies and whether it thus fulfils the criterion 'established medical science and medical practice'. There is a lack of direct evidence. The analysis of indirect evidence revealed a severe limitation in the diagnostic accuracy of the PCA3 test in comparison with the second series of biopsies. There are no data whatsoever on health-related effects of the test-plus-treatment-strategy.</p> <p>Based on the available evidence, CVZ therefore concludes that using the PCA3 test-plus-treatment-strategy on patients with an initial series of prostate biopsies without cancer, but with clinical indications of prostate cancer has not been proven to be effective. The test-plus-treatment-strategy does not comply with established medical science and medical practice and is therefore not deemed to be an insured provision (medical care) by virtue of the Health Insurance Act and relevant regulations.</p>
Type of ruling:	SpZ = outcome of assessment Zvw
Date:	22 nd August 2011
Issued to:	VWS NZA DBC-O ZN NFU NVZ CZ NVMO OMS NVU NPCF KNMG NHG
Care form:	Medical care

The original text of this Outcome of Assessment of CVZ was in Dutch. Although great care was taken in translating the text from Dutch to English, the translation may nevertheless have resulted in discrepancies. Rights may only be derived on the basis of the Dutch version of CVZ's Outcome of Assessment.

Furthermore, CVZ points out that only the summary of this report was translated. A proper understanding of all relevant considerations and facts would require familiarity with the Dutch version of this report, including all appendices.