MT82 Pipeline Embolisation Device

Erratum

The following changes are published as a supplement to the published Assessment Report Overview (ARO), and are made available by NICE to correct factual inaccuracies in the original report.

- p 7 in the ARO: The total number of patients in the PUFS study was changed:

"A report to the FDA by the sponsor (FDA 2011) described the clinical evidence at 1 year from the PUFS study: an ongoing prospective, multicentre, single-arm study of ~~107~~ 108 patients with 110 intracranial aneurysms that were wide-necked (>4 mm or no discernable neck and a size > 10 mm), large or giant (2.5– 5 mm)."

- p 8 in the ARO: The definition of a clinical outcome was added to, in line with the sponsors submission:

"Major ipsilateral stroke or neurological death as judged by Clinical Events Committee was reported in 6% (6/107) of patients in the FDA report (FDA 2011) at 180 days. Of these, 3 patients died."

- p 9 in the ARO: The absolute figures reported for the Rankin score assessment were amended:

"In the PUFS study, Rankin score assessment (a general measure of neurological function) was carried out for ~~101~~ 104 patients. The scores improved from baseline in ~~20% (21/101)~~ 20% (21/104) of patients, remained unchanged in ~~65% (70/101)~~ 67% (70/104) and deteriorated in ~~9% (10/101)~~ 10% (10/104) at 180 days follow-up (FDA 2011)."

- p 10 in the ARO: The absolute figures reported for visual field sensitivity were amended:

"The FDA report (2011) described an improvement in visual field sensitivity from baseline (not otherwise described) in ~~19% (19/101)~~ 21% (19/89) of patients, no change in ~~65% (65/101)~~ 73% (65/89) of patients and deterioration in eye function in ~~5% (5/101)~~ 6% (5/89) of patients at follow-up of 180 days."