

¹ Wilson et al., 2002.

Modified Rankin Stroke Scale

0 - No symptoms at all.

1 - No significant disability despite symptoms; able to carry out all usual duties and activities.

2 - Slight disability; unable to carry out all previous activities but able to look after own affairs without assistance.

3 - Moderate disability; requiring some help, but able to walk without assistance.

4 - Moderately severe disability: unable to walk without assistance, and unable to attend to own bodily needs without assistance.

5 - Severe disability: bedridden, incontinent, and requiring constant nursing care and attention.

² Social Security Act section 1861(r) (1)

³ Connors et al., 2004.

⁴ Creager et al., 2004.

⁵ Medicare NCD Manual section 20.7.

⁶ American Heart Association, 2004.

⁷ Topol, editor, 2002.

⁸ Ibid.

⁹ Ibid.

¹⁰ Schnieder et al., 2003.

¹¹ <http://www.americanheart.org/presenter.jhtml?identifier=4742>

¹² Schnieder et al., 2003.

¹³ O'Rourke et al., 2004.

¹⁴ Gubitz and Sandercock, 2000.

¹⁵ Barnett et al., 1999.

¹⁶ Barnett et al., 2000.

¹⁷ FDA is not bound by this Advisory Panel's recommendations.

¹⁸ Letter dated August 30, 2004 from Center for Devices and Radiological Health of the Food and Drug Administration (FDA) to Guidant Corporation
<http://www.cms.hhs.gov/goodbye.asp?URL=http://www.fda.gov/cdrh/pdf4/P040012a.pdf>

¹⁹ Federal Register Vol 68 No.187 September 26, 2003 p55,636

²⁰ Deek J., 2001.

²¹ Alberts, 2001

²² Ibid.

²³ Brooks et al., 2004.

²⁴ Ibid.

²⁵ Brooks et al., 2001.

²⁶ Ibid.

²⁷ CAVATAS, 2001.

²⁸ Yadav et al., 2004.

²⁹

<http://www.cms.hhs.gov/goodbye.asp?URL=http://www.strokecenter.org/trials/TrialDetail.asp?ref=80>

³⁰

<http://www.cms.hhs.gov/goodbye.asp?URL=http://www.strokecenter.org/trials/TrialDetail.asp?ref=468>

³¹

<http://www.cms.hhs.gov/goodbye.asp?URL=http://www.strokecenter.org/trials/TrialDetail.asp?ref=86>

³²

<http://www.cms.hhs.gov/goodbye.asp?URL=http://www.strokecenter.org/trials/TrialDetail.asp?ref=214>

³³ Gray, ACC meeting 2004.

³⁴ White et al. submission to CMS, 2004

³⁵ Hopkins, TCT meeting 2004.

³⁶ CARESS, 2003.

³⁷ Ibid.

³⁸ Ibid.

³⁹ Ouriel, Presentation FDA panel meeting, 2004.

⁴⁰ Cremonesi et al., 2003.

⁴¹ Ramee, TCT meeting 2004.

⁴² Reimers et al., 2004.

⁴³ Roubin et al., 2001.

⁴⁴ SSYLVIA, 2004.

⁴⁵ ECST investigators, 1998.

⁴⁶ Ibid.

⁴⁷ ACAS committee, 1995.

⁴⁸ MACE at

<http://www.cms.hhs.gov/goodbye.asp?URL=http://www.strokecenter.org/trials/TrialDetail.asp?ref=158>

⁴⁹ ACST group, 2004.

⁵⁰ Ibid.

⁵¹ NASCET collaborators, 1991.

⁵² Barnett et al., 1998.

⁵³ Inzitari et al., 2000.

⁵⁴ Brott et al., 2004.

⁵⁵ Ibid.

⁵⁶ Connors et al., 2004.

⁵⁷ Coward et al., 2004

[58](#) Ibid.

[59](#) Creager et al., 2004.

[60](#) O'Rourke et al., 2004.

[61](#) Halm et al., 2004.

[62](#) AHA, 1995

[63](#) Attachment 1: "Qualifications and Training Requirements" Quality Improvement Guidelines for the performance of Cervical Carotid Angioplasty and Stent Placement" Letter from SIR dated July 26, 2004 to Dr. Steve Phurrough

[64](#) Letter from SVMB, SCAI, SVS, and ACC dated July 20, 2004 to Dr. Sean Tunis.

[65](#) July 21, 2004 ASITN/CMS meeting slides

[66](#) Longstreth WT Jr, Shemanski L, Lefkowitz D, Et al

[67](#) Letter from AAN, AANS, ASITN, ASNR, CNS, AANS/CNS Cerebrovascular section, and SIR dated August 23, 2004 to Dr. Steve Phurrough

[68](#) Ouriel, presentation at FDA panel meeting 2004.

[69](#) CAPRIE trial, 2001.

[70](#) CURE trial, 2001.

[71](#) Cambria, 2004.

[72](#) AHA, 2004.

[73](#) NASCET collaborators, 2002.

[74](#) Ibid.

[75](#) Barnett et al., 1998

[76](#) ECST group, 1998.

[77](#) Ibid.

[78](#) Ouriel, presentation at FDA panel meeting 2004.

[79](#) Brooks et al., 2001.

⁸⁰ Alberts, 2001.

⁸¹ O'Rourke et al., 2004.

⁸² Gubitz, Sandercock, 2000.

⁸³ FDA NDA 20-839, 2002.

⁸⁴ Barnett, CMAJ 2004.

⁸⁵ Gubitz, Sandercock, 2000.

⁸⁶ Barnett et al., 1998.

⁸⁷

<http://www.cms.hhs.gov/goodbye.asp?URL=http://www.pubmedcentral.nih.gov/articlerender.fcgi?artid=59640>

⁸⁸ Coward et al., 2004.

⁸⁹ ACAS committee, 1995.

⁹⁰ ACST investigators, 2004.

⁹¹ O'Rourke et al., 2004.

⁹² ACAS committee, 1995.

⁹³ ACST group, 2004.

⁹⁴ Ibid.

⁹⁵ Gubitz, Sandercock, 2000.

⁹⁶ Halm et al., 2003.

⁹⁷ Brott et al., 2004.

⁹⁸ O'Rourke et al., 2004.

⁹⁹ Barnett, Lancet 2004.

¹⁰⁰ Barnett, CMAJ 2004.

¹⁰¹ Ouriel, presentation at FDA panel meeting 2004.

- [102](#) CARESS, 2003.
- [103](#) Brott et al., 2004.
- [104](#) FDA NDA 20-839, 2002.
- [105](#) SAPPHIRE data submitted by Cordis.
- [106](#) Yurdakul et al., 2004.
- [107](#) Connors et al., 2004.
- [108](#) Creager, MA, Goldstone J, et al. 2004.
- [109](#) Barnett, 2004.
- [110](#) Social Security Act section 1861(r) (1)
- [111](#) Connors et al., 2004.
- [112](#) Creager et al., 2004.
- [113](#) Medicare NCD Manual section 20.7.