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August 14, 2006

Centers for Medicare and Medicaid Services  
Attn: Beverly A. Lofton, MHA  
Ref: NCA for Vagus Nerve Stimulation for Treatment of Resistant Depression (TRD)  
(CAG-00313R)  
C1-09-06  
7500 Security Blvd.  
Baltimore, MD 21244

I am a board certified psychiatrist who has been in inpatient and outpatient psychiatry for over 14 years. During that time, I have helped my patients battle with a variety of difficult psychiatric disorders. It has been well known for many years that treatment resistant depression (TRD) is one of our most difficult clinical problems. It is my belief that virtually every psychiatrist would acknowledge that although we have made progress with TRD, much work needs to be done. Each of us has a handful of patients for whom we have no effective treatment to offer. Some have had literally dozens of medications and medication combinations, with antidepressants, mood stabilizers, augmentation strategies, anti-psychotics medications, ECT, and alternative therapies.

These individuals are unable to work, hospitalized, and sent to day treatments, individual therapy and group treatment. They utilize large amounts of prescription medications, and mental health benefits. They die by suicide, accidents, and are at increased risk of cardiac disease and disability. They have worse outcomes with other medical disorders.

Unfortunately, after a few episodes of depression, often early in life, one can predict that people with TRD will continue in a chronic or recurrent pattern. They will experience shorter remissions and face worsening odds of response to novel therapies. Each psychiatrist has a favorite arcane poly-pharmacy for such patients. My own preference is for MAOI inhibitors, alone or in combination with a tricyclic. Theoretically this combination is toxic, but if done correctly, is safe and tolerable to many patients. But these unusual combinations rarely work. "Treatment as usual" for TRD is woefully inadequate. Even heroic treatment fails to benefit these people.

Since July 2005, however, a new FDA approved treatment has been available. Adjunctive Vagus Nerve Stimulation, a safe treatment that has been in use in tens of

thousands of patients for ten years. It is low in side effects and can be offered to patients who have no other options. VNS probably operates by a mechanism of action that is simply different from anti-depressants and is likely to work even in patients who have no other choices. A well-controlled clinical trial supports the long-term benefit of VNS, as well as its safety and tolerable side effects. A comparison with treatment as usual supports the distinct difference between outcomes who have been offered VNS and those who have not.

As I write this letter, I am in the waiting room of a psychiatric hospital about 120 miles from my office. One of my patients, who has been waiting for VNS for several months, is in an acute unit here. She has completed a successful course of ECT but appears unable to be transitioned off ECT and has started maintenance. She has had recurrence of depression after two weeks off ECT and has not been in remission despite six years of anti-depressant treatment and inpatient, family, outpatient, and residential treatment. I have literally nothing to offer her besides continuing ECT indefinitely, if that works. She will need to stay in residential care for several months unless her depression improves dramatically. I have had several denials from her insurance company for VNS and will continue to pursue it until we finally file an appeal with independent physicians. At some point, she will need to stop ECT and there will be nothing to do except watch her deteriorate and hope that one of the medications that failed her before will help this time. The months-long delay, I hope, will end with her approval for VNS but then it will be months before it can be implanted and then hopefully start to give her benefit. It would be very useful to her if clear criteria for implantation of VNS existed, so that we could simply apply those criteria and agree quickly whether she is appropriate for VNS treatment. I feel that the lack of clear criteria prevents us from reaching a fair and appropriate determination of the medical necessity of VNS.

It is my belief that VNS should become a covered benefit for those who fall within well-established coverage criteria.

I am available to discuss this further or provide additional documentation if that would be helpful.

Sincerely,

David Steinman, MD, FAPA

**Curriculum Vitae**  
David Steinman, MD, FAPA  
July 1, 2006

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Specialty Certification:

- Psychiatry, American Board of Psychiatry and Neurology, December 1994  
Recertified, 2004

Licensure:

- Pennsylvania, MD-042350-L
- New Jersey, MA-54657

Honors:

- Fellow, American Psychiatric Association, 2004

Education:

Lehigh University, Bethlehem, PA

- B.A., Magna cum Laude, Premedical Science, 1982-1986

Medical College of Pennsylvania, Philadelphia, PA

- M.D., 1984-1988

Postgraduate Education:

St. Christopher's Hospital for Children-Temple Univ. Hospital, Philadelphia, PA

- Intern in Pediatrics, 1988-1989

Hospital of the University of Pennsylvania, Philadelphia, PA

- Resident in Psychiatry, 1989-1992
- Chief Resident, 1991-1992

The Philadelphia Psychoanalytic Institute, Philadelphia, PA

- Completed Training in Adult Psychoanalysis, 1992-1999

Faculty Appointments:

University of Pennsylvania School of Medicine, Philadelphia, PA

- Clinical Associate, Department of Psychiatry, 1992-2001

- Clinical Assistant Professor, Department of Psychiatry, 2001-present

Philadelphia Psychoanalytic Institute, Philadelphia, PA

- Associate Faculty, 1999-2001

The Psychoanalytic Center of Philadelphia

- Associate Faculty, 2001-present

Hospital and Administrative Appointments:

The Westmeade Center at Wyndmoor

- Staff Psychiatrist, 1993-1994
- Medical Director, 1994-1995

The Institute of Pennsylvania Hospital

- Associate Attending, 1992-1999
- Associate Director, Evaluation Unit, 1992-1993

Belmont Hospital

- Attending, 1999-2002

Committee Memberships:

Hospital of the University of Pennsylvania

- Residency Training Committee, 1991-1992
- Undergraduate Education Committee, 1991-1992
- Subcommittee on PGY 3 and 4 Didactics, 1991-1992
- Subcommittee on Psychiatry Medical Student Clerkship, 1991-1992
- Member, Psychodynamic Cluster Steering Committee, 2001-present
- Chair, Psychodynamic Cluster Steering Committee, 2006-present
- Member, Penn-Psychoanalytic Center Liaison Committee, 2006-present

The Institute of Pennsylvania Hospital

- Medical Records Committee, 1992-1995
- Brief Intensive Treatment Committee, 1993-1994

The Philadelphia Psychoanalytic Institute

- Board Member, Consultation and Referral Service, 1993-1994
- Chairman, Candidate Recruitment/Student Associates Committee, 1994-1999

The Philadelphia Psychoanalytic Society

- Secretary, 2000-2001

The Psychoanalytic Center of Philadelphia

- Secretary, 2001-2003
- Founding Chair, Colleague and Patient Assistance Committee, 2003-present

#### The American Psychoanalytic Association

- Member, Committee on Student Associates, 2001-2002
- Member, Committee on Impaired Faculty Analyst, 2004-present
- Chair, Committee on Student Associates, 2002-2006

#### A Chance to Heal Foundation

- Board Member, 2005-present

#### Teaching and Clinical Responsibilities:

- Course instruction and weekly psychotherapy supervision of third and fourth year and graduate psychiatry residents and psychology graduate students at the outpatient department at HUP and The Institute of Pennsylvania Hospital, 1992-present
- Leader of Discussion Group on Psychoanalysis, for local Student Associates of the American Psychoanalytic Association, 1998-2001
- Course instruction in Doctoring One and Two to medical students at University of Pennsylvania School of Medicine, 2000-present
- Preceptor, Fellowship Program, Psychoanalytic Center of Philadelphia, 2003-present

#### Awards:

- National Merit Scholar, 1982
- Phi Eta Sigma, 1983
- Dr. William Scholl Worldwide Scholarship, 1983
- Phi Beta Kappa, 1985
- Dr. Jean Crump Memorial Prize for Excellence in Pediatrics, 1987
- Dr. Lee Winston Silver Award for Excellence in Pediatrics, 1988
- Laughlin Foundation Merit Award for Achievement, 1992

#### Memberships in Professional Societies:

- American Psychiatric Association, Fellow, 2004
- American Psychoanalytic Association

#### Lectures:

- Series of Continuing Education Lectures on Depression, Bipolar Disorder, and Anxiety Disorders, Belmont Hospital, Fall 1998
- Workshop on Eating Disorders and Judaism at The Conference on Body Image and Judaism, University of Pennsylvania, March 21, 1999
- Lecture on Depression in Adolescents, Radnor High School Parent Teacher Organization, November 2000.

- Lecture on Treating Depression In Primary Care, to Nurse Practitioners and Primary Care Physicians, December 6, 2000.
- Lecture on Combining Psychotherapy and Psychopharmacology, Counseling Center, University of Pennsylvania, February 2001.
- Grand Rounds on Treatment Resistant Depression, Roxborough Memorial Hospital, March 19, 2002.
- CME for Physicians Assistants, on Treatment of Depression in Primary Care, June 11, 2002.
- Lecture on Physician Impairment, Department of Cardiology Fellows, Hospital of the University of Pennsylvania, August 29, 2003.
- Grand Rounds on Postpartum Disorders, with Hannah Bookbinder, MSS, LSW, Department of Obstetrics and Gynecology, Thomas Jefferson University Hospital, November 13, 2003.
- Workshop on Multiple Perspectives on the Pathological Fear Response: Integration of Psychotherapeutic and Psychopharmacologic Therapies, Annual Meeting, American Psychiatric Association, New York, May 5, 2004.
- Grand Rounds on Physician Impairment, Department of Medicine, Hospital of the University of Pennsylvania, June 15, 2004.
- Lecture on Pharmacotherapy of Depression and Anxiety, Department of Family Practice, Bryn Mawr Hospital, June 25, 2004.

Publications:

Luborsky, L., Van Ravenswaay, P., Ball, W., Steinman, D., Sprehn, G., Bryan, C. (1993). Come centrare il trattamento in ambiente psichiatrico. Uso del metodo CCRT-FIT (Trattamento ospedaliero centrato) (How to focus psychiatric hospital treatment- Use of the CCRT-FIT method (Focused Inpatient Treatment)). In Prospective Psicoanalitiche nel lavoro istituzionale (Psychoanalytic Perspectives in Institutional Work), 11, 9-16.

Steinman, D. (1997) Review of *The Self and the Ego in Psychotherapy*. In Psychoanalytic Books, 8:423-427.

Steinman, D. (1998) Review of *Theories of Psychotherapy*. In Psychoanalytic Books, 9:15-19.

Steinman, D. (1999) Review of *Psychoanalytic Versions of the Human Condition*. In Psychoanalytic Books 10:415-418.