DEPARTMENT OF HEALTH AND HUMAN SERVICES
OFFICE OF DIRECTOR

ACTION REFERRAL

TO	DATE
Bowling	12-18-06

DIRECTOR'S USE ONLY	ACTION REQUESTED
1. LOG NUMBER 060409	[ ] Prepare reply for the Director's signature DATE DUE _____
2. DATE SIGNED BY DIRECTOR Cleared 2/6/07, letter attached. ✓	[X] Prepare reply for appropriate signature DATE DUE 1-2-07
	[ ] FOIA DATE DUE _____
	[ ] Necessary Action

APPROVALS (Only when prepared for director's signature)	APPROVE	* DISAPPROVE (Note reason for disapproval and return to preparer.)	COMMENT
1.			
2.			
3.			
4.			

Lowcountry
Medical Associates
Family Practice Internal Medicine Pediatrics

CHARLES TOWNE PEDIATRICS
Carol K. Klauber, M.D.
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Anna C. Pruitt, M.D.

December 14, 2006

Dr. Marion Burton
Medical Director
South Carolina Department of
Health and Human Services
Post Office Box 8206
Columbia, South Carolina

Dear Dr. Burton:

The purpose of this letter is to request an update to the existing clinical/medical policy for reimbursement of visual evoked potential measurement (CPT 95930). Currently, there is not plan provision to reimburse pediatricians for the evaluations of bilateral visual function in young patients who are too young to verbally report the information necessary for an adequate visual assessment.

Visual evoked potential testing is a widely recognized procedure used by pediatricians to support the standard of care in their practice and to provide early diagnosis and intervention for children unable to verbalize their visual impairment. This test is covered by other insurance companies in non-specialist office environments as an acceptable method to examine children for vision defects and treatable eye conditions like Strabismus and Amblyopia. We use the Diopsys Enfant ™ Pediatric Vision Testing System for VEP testing in our office. This medical device id FDA-approved, FDA 510(k) certificate K880773 for use by physicians. The benefit of using this test on children between six months and six years of age is that it permits is that it permits the objective, scientific evaluation and referral of non-verbal children that otherwise go untreated by current dated testing methods available to pediatricians. The use of this technology advocates early intervention and treatment, thereby impacting the quality of vision and the cost over the life of the patient.

Visual evoked potential measurement has been, for many years, the objective standard for the detection of lesions affecting the visual system. VEP was defined by the American Medical Association's CPT Committee during the 1970's, and its use in infants has been described by Sokol, Zemon, and Moskowitz since the mid-1980's. Standard textbooks, such as Merritt's Neurology, Wills Eye Manual, and Goetz: Textbook of Clinical Neurology describes the use of VEP in the evaluation of children's visual pathway function. At this point in time, VEP is even relied upon as a gold standard for function and maturation in the evaluation of metabolic and growth disorders. Testing is further endorsed by other governmental agencies and professional organizations. This includes the American of Pediatricians, the American Association of Pediatric Ophthalmology and other scientific studies. See attached references.

"The mission of the American Academy of Pediatrics is to attain optimal physical, mental, and social health and well being for **all** infants, children, adolescents and young adults" per the American

Academy of Pediatrics, Committee on Children With Disabilities Role of the pediatrician in family-centered early intervention services. Pediatrics 2001; 107:1155-1157. Not only do we adhere to the mission of AAP, but also as South Carolina Medicaid providers, we follow the guidelines set forth in the Physicians Provider Manual updated 7/01/2006.

(http://www.dhhs.state.sc.us/internet/pd/manuals/Physicans/Section%202.pdf).

A review of this manual indicates there are no provisions to adequately test all children in an objective manner. While it is our intention to provide the best standard of care and appropriate referrals of our patients, the Provider Manual does not address the non-verbal pediatric population or compensate pediatricians to "treat abnormalities detect in their preliminary stages or make the appropriate referral whenever necessary" (see pages 51-52). The South Carolina Medicaid Provider Manual documents the importance of early intervention and complies with federal requirements for well-child care through Early and Periodic Diagnosis Screening and Treatment (see page 45). This includes vision assessment. And, while EPDST services are reimbursed as "all-inclusive" (page 61), page 53 recognizes that during the standardized test is not used, documentation should include the recording of observations for specific age-appropriate skills/tasks in each functional area (fine motor, gross motor, communications, self-help, social/emotional and cognitive)." The use of other neurological diagnostic procedures is defined on page 144-145 of the Physicians Provider Manual Part II. As mentioned earlier, VEP testing is an approved modality for physician use under FDA 510(k) certificate K880773.

We find the current guidelines on page 55 for infants are not consistent with meeting the needs of **all** children. "Subjective findings of the ability to regard and reach for objects, the ability to demonstrate an appropriate social smile, and to have age appropriate interactions with the examiner" are insufficient to identify neurological function of the eye for proper referral and preventive care. The Manual further states children age 4 may be tested using Snellen, Goodlite or Titmus tests. Unfortunately, an objective measurement cannot be obtained on children age four and above with the given testing methods. Infants and non-verbal children can not understand these tests, may be unable to articulate a response, or have other barriers of communication that prohibit the appropriate referral to ophthalmologists for treatment.

As Pediatricians and South Carolina Medicaid providers, it is our responsibility to provide a standard of care to all during the well-child care visit to permit us to make appropriate referrals. We ask South Carolina Medicaid to reimburse the physician separately for the additional expenses incurred by the pediatric offices that support an equal, objective, standard of care that is in the best interest of our patients' visual and developmental health.

To choose not to offer VEP testing to non-verbal children is to relegate these children to a lifetime of visual impairment.

Thank you for your consideration in this matter.

Sincerely,

Larry N. Byrd, MD

Attachment

Visual Evoked Potential Support

1. CMS/Federal

a) **Centers of Medicare and Medicaid Services (CMS)**
www.cms.hhs.gov/manuals/downloads/ncd103_xref_ncd_to_cim.pdf Medicare National coverage Determination Manual 160.10 Evoked Response Tests

b) **U.S. Preventative Services Task Force**
http://www.ahcpr.gov/clinic/uspstf/uspsvsch.htm - "The USPSTF recommends screening to detect amblyopia, strabismus, and defects in visual acuity in children younger than age 5 years."

c) **U.S. Preventative Services Task Force Ratings**
http://prevent.org/index2.php?option=com_content&task=view&id=49&_itemid=99&pop=1&page=0 The total for most health benefits received and most cost effective services is the same for Vision Screening for Children and Breast Cancer Screening.

2. Scientific Evidence

a) **Journal of AAPOS December 2004**
http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&list_uids=15616502&dopt=Abstract A New Visual Evoked Potential System for Vision Screening in Infants and Young Children; JohnW. Simon, MD, John B. Siegfried, PhD, Monte D. Mills, MD, Joseph H. Calhoun, MD and Judith E. Gurland, MD.

b) **Visual Evoked Potentials in Pediatrics** http://www.acadjournal.com/2006/V17/part1/p3/ 3d.ed.,edited by Keith H Chiappa; pp 147-156

c) **Pediatric Research**
http://www.pedresearch.org/cgi/content/abstract/28/5/485 Uauy R. Birch D, Birch E, Tyson J. Hoffman D. Effect of dietary omega-3 fatty acids on retinal function of very low-birth weight neonates. Pediatric Res 1990;28: 485-92.

d) **Pediatric Research**
www.ajcn.org/cgi/reprint/71/1/251S.pdf USDA report 1997; Effect of dietary alpha-linolenic acid on plasma and erythrocyte fatty acids, growth and visual function of preterm infants; Jensen, Prager, Chen, Fraley, Anderson, Heird

e) **Pediatrics**
pediatrics.aappublications.org/cgi/content/full/113/2/404 Pediatrics (ISSN 0031 4005), Received for publication Nov 29, 2003;accepted Nov 20, 2003; Alex R. Kempler, MD, MPH, MS, Child Health Evaluation and Research Unit, Division of General Pediatrics, University of Michigan; "Valuing Vision" pp 404-405

f) **Journal of The American Academy of Pediatrics**
http://pediatrics.aappublications.org/cgi/gca?gca=108%2F2%2F359&submit.x=86&submit.y=10 Pediatrics Vol. 108 No. 2, August 2001; Growth and Development in Preterm Infants Fed Long-Chain Polyunsaturated Fatty Acids: A Prospective, Randomized Controlled Trial: 362

g) **Documenta Opthalmologica**
http://www.springerlink.com/content/q2435p844u8255pl/?p=c5b6017b766f4fb1a3898b1cabe0fde4&pi=3 - Odom JV, Bach M, Barber C, Brigell M, Marmor MF, Tormene AP, Holder GE, Vaegan **Visual Evoked Potentials Standard (2004).** Doc Ophthalmology 2004;108:115–123

h) **Transactions of American Opthalmological Society**
http://www.pubmedcentral.nih.gov/pagerender.fcgi?artid=1298674&pageindex=26#page Electrophysiologic testing and its specific application in unsedated children. "...VER (VEP) may be of great help in diagnosing visual problems in children". "The most important question may be, Can this child see?" "If there is no obvious cause for visual loss, the question has usually been unanswered until the child is old enough to give a subjective response. In some cases, this has led to several years of missed diagnoses, with the resultant frustration of both parent and physician over the proper course of action and, the prognosis for the child". "Any abnormality of macula, optic nerve, or CNS visual system that affects central vision will result in a chance ...in the VEP". P. 425 "(VEP) development in children has been studied with the use of flash or a patterned stimulus. The latter has been used extensively to study the development of visual acuity and to follow patients with amblyopia". P. 426 "The studies would seem to confirm our opinion that (VEP) can be recorded from normal children as early as the first day of life and can be expected to be a useful test of integrity of the visual system at even this early age".

a. Sokol, S. and Dobson, V. Patern reversal visually evoked potentials in infants. Invest. Ophthalmol. Vis. Sci. 1976. 15:58-62
b. Sokol, S. and Shaterian, E. The pattern evoked cortical potential in amblyopia as an index of visual function. In Moore, S., Mein, J. and Stockbridge, L. (eds) Trans. 3rd Int. Orthoptic Congress. Miami, Symposium Specialists. 1976. pp 59-67.

j. **FDA 510(k) K043491**
www.fda.gov/cdrh/pdf4/K043491.pdf Approved VEP for use by physicians to provide information about the visual pathway function and about optical or neural abnormalities related to vision.

k. **ICSEV**
http://www.iscev.org/standards/proceduresguide.html "If specific tests are requested, they can be performed by **trained technicians**, and the results given with the normal values for the clinic." "Paediatric Cases - In many cases VEP and ERG can be done without general anaesthesia; where co-operation is poor sedation or even a general anaesthetic may be needed. General anaesthesia distorts the VEP."

3. Professional Support

a) **Clinical Pediatrics (Phila). 2006** Apr; 45(3):263-6.
http://cpj.sagepub.com/cgi/content/abstract/45/3/263 It describes the frequency of screening and the need for reimbursement. Early detection means better treatment....

b) **American Academy of Pediatrics**
http://pediatrics.aappublications.org/cgi/content/full/107/5/1155 - "The mission of the American Academy of Pediatrics is to attain optimal physical, mental, and social health and well-being for **all** infants, children, adolescents and young adults" per the American Academy of Pediatrics, Committee on Children With Disabilities Role of the pediatrician in family-centered early intervention services. Pediatrics 2001;107:1155-1157.

c) **American Academy of Pediatrics**
http://aappolicy.aappublications.org/cgi/content/full/pediatrics;108/1/192 " Early identification of children with developmental delays is important in the primary care setting. The pediatrician is the best-informed professional with whom many families have contact during the first 5 years of a child's life. Parents look to the pediatrician to be the expert not only on childhood illnesses but also on development. Early intervention services for children from birth to 3 years of age and early childhood education services for children 3 to 5 years of age are widely available for children with developmental delays or disabilities in the United States. Developmental screening instruments have improved over the years, and instruments that are accurate and easy to use in an office setting are now available to the pediatrician. This statement provides recommendations for screening infants and young children and intervening with families to identify developmental delays and disabilities."

d) **American Academy of Pediatrics**
http://aappolicy.aappublications.org/cgi/content/full/pediatrics;108/5/1215 "The mission of the American Academy of Pediatrics is to attain optimal physical, mental, and social health and well-being for all infants, children, adolescents, and young adults."[5] In support of this mission, therefore, the AAP is opposed to discrimination in the care of any patient on the basis of race, ethnicity, ancestry, national origin, religion, gender, marital status, sexual orientation, age, or disability of the patient or patient's parent(s) or guardian(s). In addition, the AAP supports the right of pediatricians to participate in the delivery of health care without discrimination on the basis of race, ethnicity, ancestry, national origin, religion, gender, marital status, sexual orientation, age, or disability. Physicians with disabilities who maintain the ability to perform the essential functions of their jobs with or without "reasonable accommodation," as defined by the Americans With Disabilities Act,[6] should not be hindered from participating in such activities."

e) **American Optometric Association Clinical Guidelines**
http://www.aoa.org/x815.xml "Clinical use of preferential looking acuity is generally very successful. Teller acuity cards can be used with infants and young children until they are ready for more subjective testing. 33,57-59 However, underestimation of visual acuity loss in patients with strabismic amblyopia on the basis of grating acuity (preferential looking acuity) limits the usefulness of this test.60-65 When in doubt, the optometrist can refer the child for electrodiagnostic testing, such as visual evoked potentials, which has been shown to be an important method for direct assessment of visual acuity in infants.66-68"

f) **American Academy of Opthalmology**
http://www.aao.org/education/library/ppp/amblyopia/prevention.cfm "Because effective treatment for amblyopia exists, it is important to identify factors that may predispose to amblyopia early in a child's life in order to improve treatment outcomes. The actual cost of the child's amblyopia diagnosis and treatment is reasonable

and the cost-benefit ratio is very low because the vision improvement lasts for a lifetime.[64] Thus, prevention and/or minimization of amblyopia by screening and prompt referrals for children with any abnormalities is worthwhile. Screening for amblyopia and strabismus, including esotropia, is usually conducted by the primary care physicians, nurses, other health professionals, or school nurses.[41]

g) **The American Association For Pediatric Opthalmology and Strabismus**
http://aapos.org/associations/5371/files/visionscreeningpolicy.pdf Recommentions p. 155 "The pediatrician and others in the office should become expert at vision testing of young children". "...all children should have their visual statuses evaluated on a regular and periodic basis". "Every effort should be made to ensure that vision screening is performed using appropriate testing conditions, instruments, and technique".

4. Insurance Policy

a) **Aetna**
http://www.aetna.com/cpb/data/CPBA0181.html - Clinical Policy Bulletins Number: 0181, "To evaluate signs and symptoms of visual loss in persons who are unable to communicate (e.g., unresponsive persons, etc.)."

5. Legislation

a) **Children's Vision Bill**
http://www.visionconnection.org/Content/ChildrensVision/News/Children'sVisionBillGains150thCosponsor.htm
S.3685 grant program to provide vision care to children

b) http://thomas.loc.gov/cgi-bin/query/C?c109:./temp/~c109r2ztDh
S.2663 amend Public Health Service Act to establish grant programs for education and outreach on newborn screening.

c) **Newborn Hearing Legislation**
http://www.ncsl.org/programs/health/hear50.htm

#409

State of South Carolina
Department of Health and Human Services

Mark Sanford
Governor

Robert M. Kerr
Director

February 6, 2007

Larry N. Byrd, M.D.
Lowcountry Medical Associates
3800 Faber Place Drive
North Charleston, South Carolina 29405

Dear Dr. Byrd:

Thank you for your letter concerning vision-screening services covered under the Early and Periodic Diagnosis, Screening, and Treatment (EPSDT) program for Medicaid-eligible children and the use of visual evoked potential testing, Current Procedural Terminology (CPT) code 95930.

As you are aware, the EPSDT program provides comprehensive and preventive health services to Medicaid-eligible children from birth to age 21 through periodic medical screenings. The required services listed under the EPSDT section of the Physician's manual are minimum requirements of each component expected to constitute an evaluation. These requirements are intended to identify any specific health or psychological issues and concerns. If it is determined that the beneficiary needs a more in depth evaluation, a referral to the appropriate specialist is required. Based on our research, the appropriate specialist for these services would be an Ophthalmologist.

While the visual evoked potential testing would provide a more extensive vision exam, this is outside the scope of the EPSDT program. Guidelines for the program state that screening components cannot be fragmented and billed separately. Therefore, the billing of an EPSDT visit and the CPT code 95930 for the same visit would not be appropriate.

If you have questions regarding this information, please contact Ms. Valeria Williams, Division Director for Physician Services, at (803) 898-2660.

Sincerely,

O. Marion Burton, MD
Medical Director

OMB/bgwd

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