

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
OFFICE OF DIRECTOR**

ACTION REFERRAL

TO <i>Myers</i>	DATE <i>3-11-08</i>
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DIRECTOR'S USE ONLY	ACTION REQUESTED
1. LOG NUMBER 000464	<input type="checkbox"/> Prepare reply for the Director's signature DATE DUE _____
2. DATE SIGNED BY DIRECTOR <i>Checked 3/13/08, letter attached</i>	<input checked="" type="checkbox"/> Prepare reply for appropriate signature DATE DUE <i>3-20-08</i>
	<input type="checkbox"/> FOIA DATE DUE _____
	<input type="checkbox"/> 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.			



MAR 11 2008

Department of Health & Human Services
OFFICE OF THE DIRECTOR

T R A N S M I T T A L

DATE 03/04/2008

TO Dr. Marion Burton

FROM Dr. Jeffrey Einhalt

FAX (903)255-8235

DEPARTMENT Palmetto Children's Urology

FAX (803)434-2834

TELEPHONE (803)434-2833

PAGES INCLUDING COVER SHEET 4

Palmetto Children's Urology

9 Medical Park Suite 420

Columbia, SC 29203

www.palmettohealth.org

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to 4 page*

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Palmetto Children's Urology

Jeffrey T. Ehreth, M.D., F.A.A.P., F.A.C.S.
Elizabeth M. Berg, A.P.R.N, M.S.N., C.R.N.P.

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MAR 11 2008

Department of Health & Human Services
OFFICE OF THE DIRECTOR

March 04, 2008

Dear Dr. Burton,

A few weeks ago, I mailed you information regarding Deflux injection for the treatment of vesicoureteral reflux for your review. I failed to include some of the information and am sending it at this time. I look forward to hearing from you and discussing this important treatment option with you.

Thank you,


Jeffrey T. Ehreth, MD

Position Statement from the American Urological Association (AUA)

Use of Deflux® in the Management of Vesicoureteral Reflux

It is the current position of the American Urological Association that endoscopic injection of the dextranomer/hyaluronic compound Deflux® is an option in the management of pediatric vesicoureteral reflux (VUR). The absence of inclusion of Deflux in the 1997 Pediatric Reflux Guidelines simply reflects the fact that it had not been introduced at that time and therefore could not have been evaluated. The contention that Deflux has not been proven to reduce urinary infections associated with reflux is inappropriate to the same extent that no other treatment modality has been shown to reduce all urinary tract infections. The resolution of reflux has been shown to reduce the incidence of pyelonephritis. Therefore to the extent that Deflux can correct VUR, it will reduce the incidence of pyelonephritis. The significantly lower morbidity associated with the use of Deflux, compared to open surgery, indicates Deflux must be considered as an important option in VUR management. The choice of management options remains with the informed family and the physician, based upon multiple factors including age, sex, reflux grade, voiding patterns, risk of renal injury, and parental preferences. To attempt to dictate specific treatment modality based upon concrete evidence is simply impossible based upon the current state of evidence. Any claim that current evidence can guide such a decision reflects a lack of understanding of the state of current evidence. As more evidence emerges, selection of specific therapy for specific patients may become more appropriate. At present, Deflux must be considered an option in the care of the pediatric patient with VUR.

Board of Directors, October 2007

Information relevant to "Injectable Bulking Agents for the Treatment of Vesicoureteral Reflux"

1. American Urological Association Position Statement "Use of Deflux[®] in the Management of Vesicoureteral Reflux", AUA Board of Directors, October 2007, available at: <http://www.auanet.org/about/policy/services.cfm#deflux> accessed 11/01/07.
2. Elder J, et al. Endoscopic Injection versus Antibiotic Prophylaxis in the Reduction of Urinary Tract Infections in Patients with Vesicoureteral Reflux. *The Current Medical Research and Opinion* Vol. 23, Supp. 4, 2007
3. Hensle T, et al. Examining Pediatric Vesicoureteral Reflux: A Real-World Evaluation of Treatment Patterns and Outcomes. *The Current Medical Research and Opinion* Vol. 23, Supp. 4, 2007
4. Koyle M, et al. Considerations Regarding the Medical Management of VUR: What Have We Really Learned? *The Current Medical Research and Opinion* Vol. 23, Supp. 4, 2007
5. Conway P, et al. Recurrent Urinary Tract Infections in Children: Risk Factors and Association with Prophylactic Antimicrobials *JAMA*. 2007; 298:179-186
6. Jung C, et al. Subureteral Injection of Dextranomer/Hyaluronic Acid Copolymer for Persistent Vesicoureteral Reflux Following Ureteroneocystostomy. *J Urol* 2007; 177: 312-5.
7. Wadie G, et al. The Deflux Procedure Reduces the Incidence of Urinary Tract Infections in Patients with Vesicoureteral Reflux *J of Laparoscopic & Advanced Surgical Techniques*. Vol. 17, No. 3, 2007.
8. Stenberg A, et al. Treatment of VUR in children using NASHADIX (Deflux) A Long-term observational study. *J of Ped Urol* (2007) 3, pgs 80-85
9. Lendway T, et al. The Evolution of Vesicoureteral Reflux Management in the Era of Dextranomer/Hyaluronic Acid Copolymer: A Pediatric Health Information System Database Study. *J Urol*, 176: 1864, 2006
10. Kitchens D, et al. Endoscopic Injection of Dextranomer/Hyaluronic Acid Copolymer to Correct Vesicoureteral Reflux Following Failed Ureteroneocystostomy. *J Urol* 2006; 176: 1861-1863.
11. Benoit RM et al. The Cost-Effectiveness of Dextranomer/Hyaluronic Acid Copolymer for the Management of Vesicoureteral Reflux. 1: Substitution for Surgical Management. *J Urol* 2006; 176: 1588-92
12. Elder J, et al. Endoscopic Therapy for Vesicoureteral Reflux: A Meta Analysis. 1. Reflux Resolution and Urinary Tract Infection. *J of Urol* 2006; 175: 716-722
13. Yu R, et al. Treatment of Vesicoureteral Reflux Using Endoscopic Injection of Nonanimal Stabilized Hyaluronic Acid/Dextranomer Pediatrics, Initial Experience in Pediatric Patients by a Single Surgeon. *Pediatrics* 2006; 118: 698-703
14. Perez-Brayfield M, et al. Endoscopic Treatment with Dextranomer/Hyaluronic Acid for Complex Cases of Vesicoureteral Reflux. *J of Urol*; 2004; 172
15. Kobelt G, et al. The Cost Effectiveness of Endoscopic Injection of Dextranomer/Hyaluronic Acid Copolymer for Vesicoureteral Reflux. *J of Urol April* 2003 Vol 169: 1480-1485
16. Capozza N, et al. Dextranomer/Hyaluronic Acid Copolymer Implantation for Vesico-Ureteral Reflux: A Randomized Comparison with Antibiotic Prophylaxis. *J Pediatr* 2002; 140: 230-4.
17. Rushion G, et al. Parental Preferences in the Management of Vesicoureteral Reflux. *J Urol*, 200; 166: 240.
18. Stenberg A, et al. Injectable Dextranomer-based Implant: Histopathology, Volume Changes and DNA Analysis. *Scand J Urol Nephrol* 1999; 33: 355-61

Relevant Clinical Reference 11-28-07

March 11, 2008

Jeffrey Ehreth, M.D.
Palmetto Children's Urology
9 Medical Park, Suite 420
Columbia, SC 29203

RE: Use of Deflux[®] in the Management of Vesicoureteral Reflux

Dear Dr. Ehreth:

Thank you for forwarding the additional information regarding the management of vesicoureteral reflux in children utilizing this dextranomer/hyaluronic compound. The American Urologic Association Board of Directors' statement regarding the difficulties with universally prescribed treatment modality is based on concrete evidence is very appropriate. It does appear that Deflux[®] offers a significant advantage in some children.

I would like to consider exploring this further with you. We can set up a conference call or a meeting in the next few weeks. I am copying my DHHS staff colleagues so that they can begin to check calendars for an appropriate time.

Thank you again for corresponding regarding this matter and for forwarding the additional information. I look forward to further dialogue.

Sincerely,

O. Marion Burton, M.D.
Medical Director

OMB/klc

Cc: Zenovia Vaughn
Penny Faulkenberry
Melanie Giese
Felicity Meyers



State of South Carolina
Department of Health and Human Services

Log # 464 ✓

Mark Sanford
Governor

Emma Forkner
Director

March 13, 2008

Jeffrey Ehreth, M.D.
Palmetto Children's Urology
9 Medical Park, Suite 420
Columbia, SC 29203

RE: Use of Deflux[®] in the Management of Vesicoureteral Reflux

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Thank you again for corresponding regarding this matter and for forwarding the additional information. I look forward to further dialogue.

Sincerely,

A handwritten signature in black ink, appearing to read "O. Marion Burton".

O. Marion Burton, MD
Medical Director

OMB/bk