

# A Clinical and Coding Overview of OASIS<sup>®</sup> Wound Matrix and OASIS<sup>®</sup> Burn Matrix

Kathleen D. Schaum, MS; and Kathleen L. Farley, MS, RN

**O**ASIS<sup>®</sup> Wound Matrix is a natural extracellular matrix that has an intact three-dimensional structure that replaces the body's missing or failing extracellular matrix. OASIS contains key components of the dermal extracellular matrix such as collagen, elastin, glycosaminoglycans, glycoproteins, and proteoglycans. It is derived from porcine small intestinal submucosa and retains the biological structure of extracellular molecules to provide the scaffolding to support cell proliferation and adherence.<sup>1</sup>

**Clinical information.** OASIS should be considered a logical next-step addition to standard of care. It has been shown to significantly improve wound management<sup>2</sup> and possesses several practical features that may make it conducive to clinical use — ie, OASIS is stored at room temperature, has a shelf life of up to 2 years,<sup>3</sup> can be applied weekly, and previously placed OASIS does not need to be removed. Additionally, the cost of OASIS is reasonable: in recent clinical studies, the average cost of 12 weeks of OASIS (product only) for use in venous leg ulcers and diabetic foot ulcers was \$320 and \$250, respectively.<sup>2,4</sup>

The efficacy and safety of OASIS were examined in a randomized clinical trial for the treatment of full-thickness venous leg ulcers.<sup>2</sup> Patients were randomly assigned to weekly topical administration of OASIS plus standardized compression therapy or non-adherent dressing and compression therapy (standard of care). After 12 weeks, 55% of patients in the OASIS group had been successfully managed as compared to 34% of patients in the group that received standard of care only ( $P = 0.0196$ ). OASIS was well tolerated and no significant between-group differences in treatment-related adverse events were reported. Based on these data, the authors concluded that OASIS, when used as an adjunctive therapy, significantly improves wound management of chronic venous leg ulcers over standard therapy alone. Thus, OASIS combined with standard of care may be a logical choice for the next step in therapy for difficult-to-heal wounds.

Many peer-reviewed, scientific articles show that OASIS contains many additional extracellular matrix factors. In addition to collagen, the presence of



**OASIS<sup>®</sup> Wound Matrix is a natural extracellular matrix that has an intact three-dimensional structure that replaces the body's missing or failing extracellular matrix.<sup>1</sup>**

several different types of glycosaminoglycans, including hyaluronic acid, have been described.<sup>5</sup> Glycosaminoglycans, such as fibronectin, also have been reported,<sup>6</sup> along with the presence and activity of other matrix-associated factors.<sup>3,7-10</sup> All of these components are constituents of the natural extracellular matrix and contribute to its natural tissue composition, structure, and function. The literature shows that the extracellular matrix of which OASIS is comprised is largely unaltered from its native, three-dimensional state and composition.<sup>9,10</sup>

**Classification/Coding.** The Food and Drug Administration (FDA) recently revised the OASIS clearance and issued a new 510(k) K061711 in July 2006. The common name was changed from *topical wound dressing* to *animal-derived extracellular matrix wound care product* to acknowledge the product's inherent properties. For the same reasons, the class for OASIS changed from *Class II* to *Unclassified*. Also, the name was changed from *SIS Wound Dressing II* to *OASIS Wound Matrix*.

OASIS is recognized by the *United States Pharmacopeia* (USP). The monograph for "Small Intestinal Submucosa Wound Matrix" was published in *USP29-NF24*<sup>11</sup> and became official January 1, 2006. The USP monograph includes specifications that OASIS contains glycosaminoglycans and other matrix components. It also specifies that components of OASIS are able to stimulate

OASIS has been shown to significantly improve wound management and possesses several practical features that may make it conducive to clinical use.

cell differentiation in a cell culture assay, an indicator of bioactivity. These specifications differentiate OASIS from collagen dressing material; purified collagen alone does not contain these components and is unable to stimulate cell differentiation in this cell culture assay.

**Evolution of OASIS coding.** Before the clinical trials and USP monograph were published, the Centers for Medicare and Medicaid Services (CMS) assigned OASIS products to the HCPCS codes for collagen dressings. On June 3, 2005, the CMS SADMERC informed the manufacturer and distributor that OASIS products were removed from the surgical dressing HCPCS codes and assigned to the J3590 *Unclassified Biologics* code.

On October 24, 2005, the CMS HCPCS Workgroup informed the manufacturer and distributor that J7341 — *Dermal (substitute)*

## Measurement Guide for OASIS

Some providers have trouble determining the number of square centimeters that are purchased for each application. To calculate square centimeters in a piece of OASIS, multiply the length times the width of the piece that is closest to the size of the wound.

For example:

3 cm x 3.5 cm piece of OASIS = 10.5 cm<sup>2</sup>

3 cm x 7 cm piece of OASIS = 21 cm<sup>2</sup>

7 cm x 10 cm piece of OASIS = 70 cm<sup>2</sup>

7 cm x 20 cm piece of OASIS = 140 cm<sup>2</sup>

*tissue of non-human origin, with or without other bioengineered or processed elements, with metabolically active elements, per square centimeter* — was created and is appropriate for OASIS products. On December 7, 2005 the CMS Division of Outpatient Care Center for Medicare Management informed the manufacturer and distributor, "HCPCS code J7341 appropriately describes OASIS® Wound Matrix and OASIS® Burn Matrix. Therefore, you may advise hospitals to bill for these biologics using HCPCS code J7341. In calendar year (CY) 2006, HCPCS J7341 will receive separate payment under the Outpatient Prospective Payment System (OPPS), and payment will be determined using the Average Sales Price (ASP) methodology as described in the CY 2006 final rule with comment period."

On November 17 and 18, 2005, 37 new and five revised skin replacement surgery and application of skin substitute codes were released at the AMA CPT® 2006 Coding Symposium. Richard J. Kagan, MD, FACS, Chief of Staff, Shriners Burns Hospital; Director, University Hospital Burn Center; and Professor of Surgery, University of Cincinnati Medical College of Medicine, Cincinnati, Ohio reviewed the new/revised codes approved by the CPT Editorial Panel. Dr. Kagan reminded symposium attendees that xenografts are tissue transplanted from one species to another species and presented the new CPT® definition of xenografts — ie, "Application of a non-human skin graft or biologic wound dressing (eg, porcine tissue or pigskin) to a part of the recipient's body following debridement of the burn wound or area of traumatic injury, soft tissue infection and/or tissue necrosis, or surgery." Dr. Kagan reviewed the six xenograft CPT® codes. Codes 15400 and 15401 were revised for xenograft skin (dermal) for temporary wound closure on the trunk, arms, or legs. New codes 15420 and 15421 were added to address xenograft skin (dermal) for temporary wound closure on the face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits. New codes 15430 and 15431 represent *acellular*

*xenograft implants*. Dr. Kagan displayed a chart with the brand names of the products represented by the new CPT® codes — brand names provided as examples for 15430 and 15431 were OASIS® Wound Matrix and SURGISIS®.

When the 2006 Medicare Resource Based Relative Value Scale (RBRVS) Physician Fee Schedule was released, the CMS assigned a fee to 15430; the rate for 15431 was left to Carrier discretion because the physician community did not return any RUC surveys for 15431. With the release of the 2006 OPPS Final Rule was released, the CMS assigned 15430 and 15431 to Ambulatory Payment Classification (APC) group 0025 and designated a fee to that APC group.

HCPCS code J7341 has been included in every quarterly update of the ASP file since the CMS began listing it on January 1, 2006. The CMS also assigned J7341 to APC group 1707 and listed the ASP for APC group 1707 in Addendum B of the OPPS. The fee for APC group 1707 has been updated every quarter based on the updated ASP file.

The existence of codes does not guarantee coverage or payment by any payor. However, providers' outcomes and cost-effectiveness, patients' positive experience with the use of the OASIS products, the FDA classification as an "unclassified medical device," the USP monograph publication, the creation of CPT® and HCPCS codes to represent the product and its application, and the inclusion of prices on the RBRVS Physician Fee Schedule, the ASP File, and the OPPS File should provide strong rationale for prior authorization and positive local coverage determinations.

CPT is a registered trademark of the American Medical Association.

OASIS and SURGISIS are registered trademarks of Cook Biotech, Inc.

*Kathleen D. Schaum, MS, is the Reimbursement Director of Healthpoint, Ltd, Fort Worth, Tex. Kathleen L. Farley, MS, RN, is the Director of Clinical Education of Healthpoint, Ltd, Fort Worth, Tex.*

DISCLAIMER: Due to the rapidly changing nature of the law and reliance on information provided by outside sources, the information provided herein does

not constitute a guarantee or warranty by Healthpoint, Ltd, that coverage or payment will be provided. This information is provided "AS IS" and without any other warranty or guarantee, expressed or implied, as to completeness, accuracy, fitness for a particular purpose, or otherwise. This information has been compiled based on information gathered from many primary and secondary sources, including the American Medical Association, certain Medicare Carriers, and certain Medicare Fiscal Intermediaries. Physicians and other providers must confirm or clarify coding from their respective payers, as each payer may have differing Local Coverage Determinations. Physicians and providers are responsible for accurate documentation of patients' conditions and for reporting of procedures and products in accordance with particular payer requirements. It is recognized that the meaning, usage, and legal definitions of some specific words in this document differ between agencies and organizations. In this article every attempt has been made to use the wording as issued by the respective agency or organization. The author and Healthpoint disclaim promotion outside the context of the quote.

#### References

1. Brown-Etris M, Cutshall W, Hiles MC. A new biomaterial derived from small intestine submucosa and developed into a wound matrix device. *WOUNDS*. 2002;14:150-166.
2. Mostow EN, Haraway GD, Dalsing M, Hodde JP, King D. Effectiveness of an extracellular matrix graft (OASIS Wound Matrix) in the treatment of chronic leg ulcers: a randomized clinical trial. *J Vasc Surg*. 2005;41:856-862.
3. Hodde JP, Ernst DMJ, Hiles MC. An investigation of the long-term bioactivity of endogenous growth factor in Oasis Wound Matrix. *J Wound Care*. 2005;14:23-25.
4. Niezgoda JA, Van Gils CC, Frykberg RG, Hodde JP; OASIS Diabetic Ulcer Study Group. Randomized clinical trial comparing OASIS wound matrix to Regranex Gel for diabetic ulcers. *Adv Skin Wound Care*. 2005;18(5):258-266.
5. Hodde JP, Badylak SF, Brightman AO, Voytik-Harbin, SL. Glycosaminoglycan content of small intestinal submucosa: a bioscaffold for tissue replacement. *Tissue Eng*. 1996;2:209-217.
6. McPherson TB, Badylak SF. Characterization of fibronectin derived from porcine small intestinal submucosa. *Tissue Eng*. 1998;4:75-83.
7. Hodde JP, Hiles MC. Bioactive FGF-2 in sterilized extracellular matrix. *WOUNDS*. 2001;13:195-201.
8. McDevitt CA, Wildey GM, Cutrone RM. Transforming growth factor beta-1 in a sterilized tissue derived from the pig small intestine submucosa. *J Biomed Mater Res*. 2003;67A:637-640.
9. Hodde JP, Janis AD, Ernst DMJ, Zopf D, Sherman DA, Johnson C. Effects of sterilization on an extracellular matrix scaffold: Part I. Composition and matrix architecture. *J Mater Sci Mater Med*. In press.
10. Hodde JP, Janis A, Hiles MC. Effects of Sterilization on an extracellular matrix scaffold: Part II. Bioactivity and matrix interaction. *J Mater Sci Mater Med*. In press.
11. U.S. Pharmacopeia. USP29-NF24:2268--2270.

For CE/CME accredited courses available 24/7, including more information on extracellular matrix, check out the new course, **The Biology of the Chronic Wound**, now available at [www.TheWoundInstitute.com](http://www.TheWoundInstitute.com)®.

*TheWoundInstitute.com*®, your source for interactive wound care education.



When wounds fail to progress after  
2-4 weeks with your standard care...

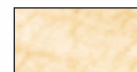
OASIS<sup>®</sup> enables the body to  
get things moving again.

### Simple application, proven results<sup>1</sup>

- Significantly improves wound management<sup>1</sup>
- Supports the body's natural wound response by replacing the missing extracellular matrix (ECM)<sup>2</sup>
- An easy addition to your standard wound care
- In the office, off the shelf for once-weekly application
- In a recent clinical study, the average cost of OASIS<sup>®</sup> for 12 weeks in venous stasis ulcers was \$320<sup>1</sup>
- Has relevant HCPCS (J) and CPT<sup>®</sup> codes

INTRODUCE

**OASIS<sup>®</sup>**  
WOUND MATRIX



Sheet of OASIS<sup>®</sup> Wound Matrix

Get things moving again

**HEALTHPOINT<sup>®</sup>**

A DFB COMPANY

1-800-441-8227

www.healthpoint.com



**References:** 1. Data on file. Healthpoint, Ltd, Fort Worth, TX 76107.  
2. Brown-Etris M, Cutshall WD, Hiles MC. A new biomaterial derived from small intestine submucosa and developed into a wound matrix device. *Wounds*. 2002;14:150-166.

OASIS is a registered trademark of Cook Biotech, Inc.  
CPT is a registered trademark of the American Medical Association.

© Copyright 2006, Healthpoint, Ltd. Printed in USA TM0684-0506