

# ▶ CRITICAL ACCESS HOSPITALS AND WOUND CARE

MEETING PATIENTS' NEEDS

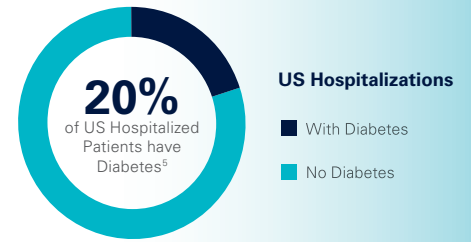


National Rural  
Health Association

VIVEX<sup>®</sup>  
BIOLOGICS

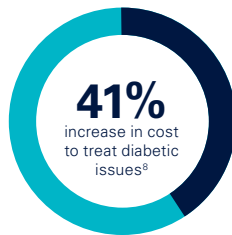
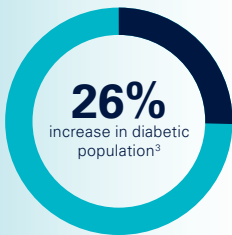
## ➤ CRITICAL ACCESS HOSPITAL CHALLENGES IN WOUND CARE

Critical Access Hospitals (CAHs) play an important role in national health care, providing rural patient populations with vital health care services. Communities served by CAHs face significant challenges because patients frequently encounter transportation limitations when it comes to receiving specialized treatment for wound care. The number of patients in need of wound care treatment and service in the CAH setting is rising in parallel with the national increase in chronic health care conditions, such as obesity and diabetes.



Wound care clinical solutions enable CAHs to provide optimal care and maintain efficient service to a patient population afflicted by morbidities associated with chronic wounds caused by diabetes. A chronic wound is any wound that fails to heal in an expected time frame (~30 days). In 2019, 6.5 million Americans had chronic wounds, which represents a cost burden of \$39B annually.<sup>1</sup>

**Diabetic Population Increase 2007-2013**



Currently, approximately 13% of the US population is afflicted with diabetes,<sup>2</sup> and that number is growing. Between 2007 and 2013, the number of diabetic individuals in the US increased by 26%.<sup>3</sup> Multiple chronic wounds are associated with diabetes, including diabetic foot ulcers (DFU), venous leg ulcers (VLU) and pressure ulcers (PU), and rural populations are particularly afflicted with these morbidities. Up to 25% of patients with diabetes will develop a DFU at some point in their lifetime.<sup>4</sup>

With more than 20% of US hospitalization being patients with diabetes,<sup>5</sup> these chronic wounds represent a significant economic burden to the health care system and the CAHs. Average direct medical costs for patients with diabetes has been observed to be 2.3X higher than those without the disease.<sup>6</sup> In fact, by 2017, 1 out of every 4 health care dollars spent in the US was on diabetic care.<sup>7</sup> The average treatment cost of a DFU is \$29,373 and the mean one-year cost from a health care public payer perspective is \$44,200.<sup>8</sup> Indeed, inpatient admissions alone account for 74-77% of total costs attributed to lower extremity complications in diabetes.<sup>9,10</sup>

**UP TO 25%**

of diabetic patients will experience a foot ulcer at some point in their lifetime<sup>4</sup>

**15%**

will require lower extremity amputations<sup>1</sup>

**\$44,200<sup>8</sup>**

Mean one-year cost to treat DFU from a health care public payer perspective

**DFUs rank #1**

as conditions associated with direct Emergency Department and Inpatient Admission hazard ratios<sup>11</sup>

**DFIs rank #2**  
(Diabetic Foot Infections)

**6.7 Million**

DFU and DFI ambulatory care diabetic foot cases in the US between 2007 & 2013<sup>11</sup>

Additional expenses associated with other common diabetic patient complications, such as pressure ulcers (PU), include hospital stays that average 3X longer than diabetic patients who do not have PUs (14.1 days vs. 5 days), and are 3X more likely to lead to a discharge to a long-term care facility (53.4% vs. 16.2%).<sup>9</sup> Venous leg ulcers (VLU) are often associated with an intense chronicity that leads to these ulcers remaining open for months, sometimes even years.<sup>12</sup> In 2014, it was estimated that approximately \$15 billion was spent in the treatment of venous ulcers,<sup>14</sup> (VU) representing yet another expense associated with chronic wounds and wound care.



**~\$15 Billion** to treat Venous Ulcers in 2014<sup>10</sup>

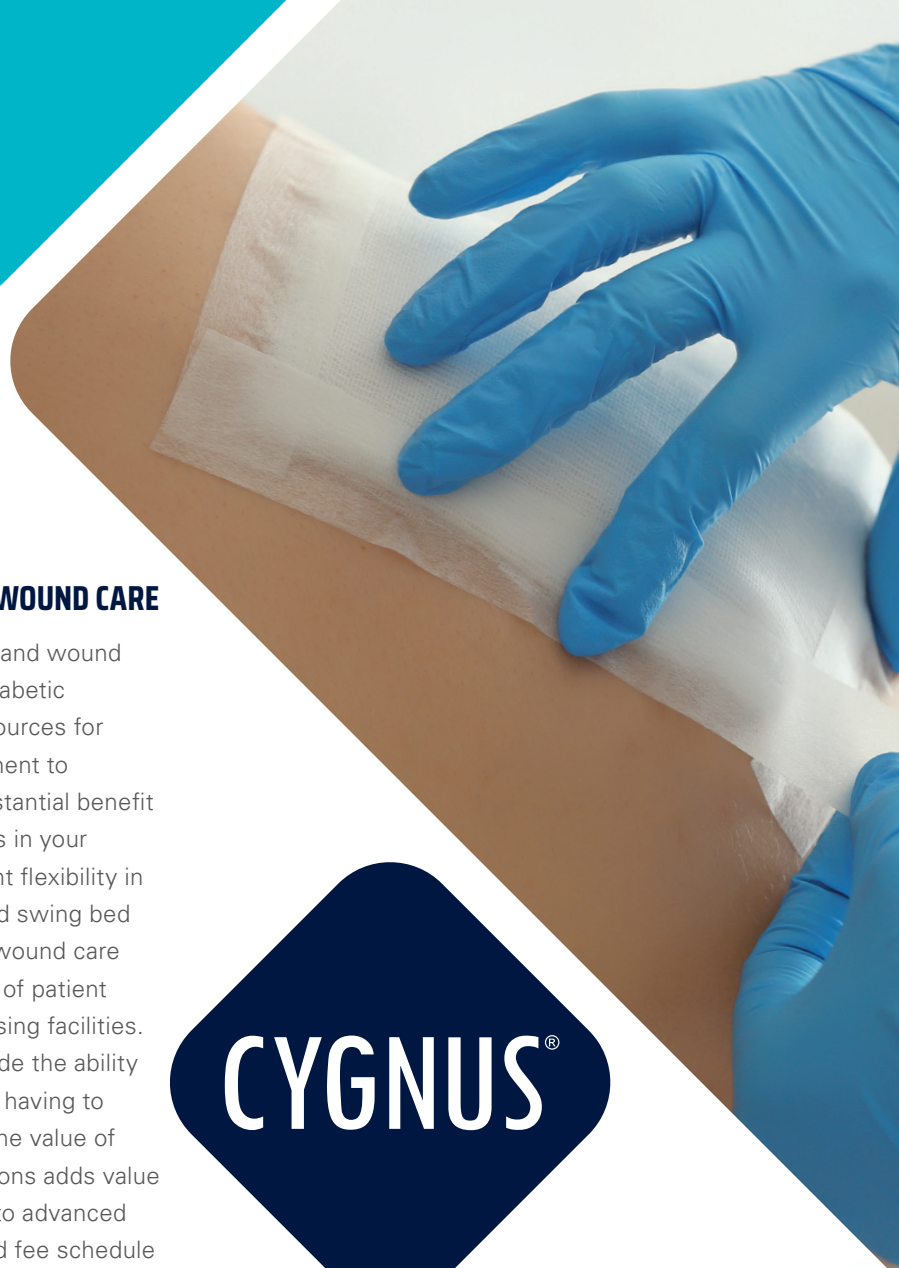
VIVEX Biologics offers clinical solutions that allow you to provide the best care for your patients suffering from diabetic or chronic wounds. VIVEX is a leading regenerative medicine company specializing in the development of naturally sourced treatment options and solutions that improve clinical, surgical, and therapeutic patient care through innovation. Leveraging the resources of the nation's oldest civilian tissue bank, VIVEX partners with medical professionals to provide innovative treatment options by channeling the body's inherent healing qualities.

VIVEX focuses on core products and new technologies to meet the evolving biologic needs of surgeons and our patients while sustaining our 50+ year commitment to service. Due to its leadership in the field, VIVEX has distributed over 2 million allografts without a case of disease transmission, an unmatched history of safety in the industry.

**50 years**  
of regeneration







## ► POTENTIAL SOLUTIONS AND PLANNING FOR WOUND CARE

Increased demands for chronic wound treatment and wound care services, especially those associated with diabetic patients, are challenging the limited staff and resources for CAHs. Establishing a proper plan with a commitment to providing wound care services can provide a substantial benefit to both the patients and the medical professionals in your institution. These benefits could provide treatment flexibility in outpatient clinics, outpatient operating rooms, and swing bed units with minimal start up supply costs. A solid wound care plan will enable multiple care settings as sources of patient referrals from rural health clinics and skill and nursing facilities. Successful wound care treatment plans will provide the ability to treat your patient population locally rather than having to refer them to facilities that may be hours away. The value of patient satisfaction and compliance to local solutions adds value to your community and hospital. Further, access to advanced modalities that have a published HCPCS code and fee schedule for reimbursement benefit your institution.



## ► PARTNERING FOR PATIENT OUTCOMES



Including a focus on wound care for your local community provides an opportunity to enhance clinical outcomes for chronic wounds and potentially increase patient compliance. VIVEX offers products in varying configurations to provide physicians options that could be considered for treatment in general wound care and for chronic wounds.

VIVEX offers multiple amniotic allograft options to meet the needs of the medical community. These products include a multi-layer membrane allograft maintaining the amnion layer, its intermediate/spongy layer, and the chorion layer of the amniotic sac, which are never separated during processing, and a thicker umbilical cord membrane amniotic allograft tissue suitable for suturing. VIVEX's amniotic allograft products are intended for homologous use to provide a soft tissue barrier and covering for wound repair.

## ➤ REIMBURSEMENT INFORMATION FOR CRITICAL ACCESS HOSPITALS

For additional information or questions regarding insurance coverage and reimbursement, please contact VIVEX Reimbursement support at 877.475.0888 or [reimbursement@vivex.com](mailto:reimbursement@vivex.com).

### CAH MEDICARE PAYMENTS\*

#### DESCRIPTION

CAHs are paid for most inpatient and outpatient services to Medicare patients at 101% of reasonable costs.

Medicare does not include CAHs in the hospital Inpatient Prospective Payment System (IPPS) or the hospital Outpatient Prospective Payment System (OPPS). This means that Medicare does not package the payment for skin substitutes into the application code. Therefore, Medicare reimburses for the application of (15271-15278) and for the skin substitute product (Q4170).

Medicare pays CAH services according to Part A and Part B deductible and coinsurance amounts and does not limit most of the 20% CAH Part B outpatient services copayment charges by the Part A inpatient deductible amount.

The Centers for Medicare & Medicaid Services (CMS) encourages CAHs to help patients understand their services' charges and potential financial obligation.

### COMMON PROCEDURAL TERMINOLOGY (CPT) AND (HCPCS) CODES\*\*

CODE	DESCRIPTION
Q4170	CYGNUS per sq. cm
15271	Application of a skin substitute graft to trunk, arms, legs, total wound surface up to 100 sq. cm; first 25 sq. cm or less wound surface area
+15272	Each additional 25 sq. cm wound surface area, or part thereof (list separately in addition to code for primary procedure)
15273	Application of a skin substitute graft to trunk, arms, legs, total wound surface area greater than or equal to 100 sq.cm; first 100 sq. cm of wound surface area, or 1% of body area of infants and children
+15274	Each additional 100 sq. cm of wound surface area, or part thereof, or each additional 1% of body area of infants and children, or part thereof (list separately in addition to code for primary procedure)
15275	Application of a skin substitute graft to face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits, total wound surface area up to 100 sq. cm; first 25 sq. cm or less of wound area
+15276	Each additional 25 sq. cm of wound area, or part thereof (list separately in addition to code for primary procedure)
15277	Application of a skin substitute graft to face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits, total wound surface area greater than or equal to 100 sq. cm; first 100 sq. cm or less of wound area, or 1% of body area of infants and children
+15278	Each additional 100 sq. cm or less of wound area, or part thereof, or each additional 1% of body area of infants and children, or part thereof (list separately in addition to code for primary procedure)

\*CAH Medicare Learning Network Critical Access Hospital, ICN MLN006400 July 2019

\*\*Current Procedure Terminology (CPT) © 2020 American Medical Association. All Rights reserved.

## ➤ CYGNUS WOUND CARE SOLUTIONS

CYGNUS® is a family of amniotic allografts processed to retain the inherent mechanical properties of amniotic tissue and rich supply of extracellular matrix, growth factors, and cytokines.<sup>15,16</sup>



### CYGNUS® MATRIX

Multi-layer membrane allograft maintaining the amnion layer, its intermediate/spongy layer, and the chorion layer of the amniotic sac, containing inherent growth factors, collagen, cytokines, and extracellular matrix.<sup>15,16</sup>

Multi-layer amniotic membrane allograft, ~400µm (0.4mm) thick, up to 4X thicker than the single amnion layer

The intermediate/spongy layer contains a meshwork of mostly type III collagen which plays a prominent role in cutaneous wound repair<sup>17,18</sup>

5-year shelf life at room temperature storage

No upfront preparation – hydrates rapidly in surgical site

Ideal for both internal and external application

Available in a variety of sizes and shapes to meet clinical needs and allow use throughout the course of wound repairs

Available circular shape saves time by reducing the need to trim and associated potential to waste tissue

### CYGNUS® MAX

Comprised of the umbilical cord membrane, this tissue is the thickest of the VIVEX dehydrated amniotic allograft products and is robust enough to be sutured in place.

Thick umbilical cord membrane, ~400µm (0.4mm) thick, up to 4X thicker than the single amnion layer

5-year shelf life at room temperature storage

No upfront preparation — hydrates rapidly in surgical site

Tissue can be sutured into place

Excellent handling properties

# CYGNUS®

## MAX XL



Comprised of fenestrated umbilical cord membrane, increasing the available allograft size to cover a larger wound while also allowing the wound to drain.

Thick umbilical cord membrane, 400µm (0.4mm) thick, up to 4X thicker than the single amnion layer

5-year shelf life at room temperature storage

No upfront preparation — hydrates rapidly in surgical site

Tissue can be sutured into place

Excellent handling properties

Fenestrated to allow for wound drainage and increases the size of the umbilical cord membrane

## ► ORDERING INFORMATION

Product HCPCS Code: Q4170 (CYGNUS) per square centimeter

### CYGNUS® MATRIX

CODE	DESCRIPTION	SIZE	SQ. CM.
CAP020200S	CYGNUS® Matrix Amnion Allograft	2x2cm	4
CAP020300S	CYGNUS® Matrix Amnion Allograft	2x3cm	6
CAP030300S	CYGNUS® Matrix Amnion Allograft	3x3cm	9
CAP040400S	CYGNUS® Matrix Amnion Allograft	4x4cm	16
CAP040600S	CYGNUS® Matrix Amnion Allograft	4x6cm	24
CAP070700S	CYGNUS® Matrix Amnion Allograft	7x7cm	49
CAP015000S	CYGNUS® Matrix Amnion Allograft Disk	15mm Disk	2
CAP025000S	CYGNUS® Matrix Amnion Allograft Disk	25mm Disk	5
CAP035000S	CYGNUS® Matrix Amnion Allograft Disk	35mm Disk	10
CAP045000S	CYGNUS® Matrix Amnion Allograft Disk	45mm Disk	16
CAP055000S	CYGNUS® Matrix Amnion Allograft Disk	55mm Disk	24
CAP065000S	CYGNUS® Matrix Amnion Allograft Disk	65mm Disk	33

### CYGNUS® MAX

CODE	DESCRIPTION	SIZE	SQ. CM.
CAM020200S	CYGNUS® Max Umbilical Cord Membrane	2x2cm	4
CAM020300S	CYGNUS® Max Umbilical Cord Membrane	2x3cm	6
CAM020400S	CYGNUS® Max Umbilical Cord Membrane	2x4cm	8

### CYGNUS® MAX XL

CODE	DESCRIPTION	SIZE	SQ. CM.
CAX020300S	CYGNUS® Max XL Fenestrated Umbilical Cord Membrane	2x3cm	6
CAX030300S	CYGNUS® Max XL Fenestrated Umbilical Cord Membrane	3x3cm	9
CAX030800S	CYGNUS® Max XL Fenestrated Umbilical Cord Membrane	3x8cm	24
CAX040400S	CYGNUS® Max XL Fenestrated Umbilical Cord Membrane	4x4cm	16
CAX040600S	CYGNUS® Max XL Fenestrated Umbilical Cord Membrane	4x6cm	24
CAX040800S	CYGNUS® Max XL Fenestrated Umbilical Cord Membrane	4x8cm	32
CAX050700S	CYGNUS® Max XL Fenestrated Umbilical Cord Membrane	5x7cm	35



VIVEX Biologics uses reasonable efforts to provide accurate information herein, but this information should not be construed as providing clinical advice, dictating reimbursement policy, guaranteeing coverage, or as a substitute for the judgment of a health care provider. It is always the health care provider's responsibility to determine the appropriate codes, charges for services, and use of modifiers for services rendered and to verify coverage with payers, including the applicability of any non-coverage policies that may exist. Reimbursement laws, regulations, and payer policies change frequently without notice, and VIVEX Biologics assumes no responsibility for the timeliness, accuracy, or completeness of the information provided. It is highly recommended that health care providers consult with their payers, coding specialists, and/or legal counsel regarding coverage, coding, and payment issues.

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