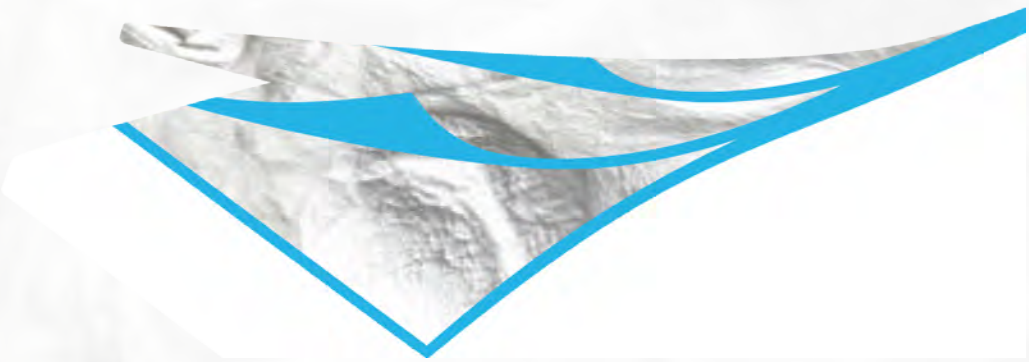
WORLD REACH HEALTH

DERMABIND TL™ INTRODUCTION PACKET

ADVANCING WOUND CARE
WITH PLACENTA-BASED
TRIPLE LAYER ALLOGRAFTS



WORLD REACH HEALTH LLC

847-220-4664 sales@worldreachhealth.com www.worldreachhealth.com 3501 W. Algonquin Rd., Suite 135, Rolling Meadows, IL 60008

WORLD REACH HEALTH

DERMABIND TL™ INTRODUCTION PACKET

TABLE OF CONTENTS

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AmnioBind

Sterilized, Dehydrated Amniotic Allograft

DESCRIPTION

AmnioBind is a dehydrated amniotic membrane covering that preserves the comprehensive collagen matrix, glycoconjugates, and glycosaminoglycans.

THE AMNIOBIND PROCESS

AmnioBind undergoes a proprietary preservation method, which retains all native layers of the placental membrane, including the amnion and chorion with the spongy layer intact, unlike many placental allografts on the market.

The AmnioBind process does not use unnecessary chemicals, antibiotics or preservatives and is never frozen.

The finished product is physician-friendly, durable, easily applied to a wound and can be stored at room temperature for up to 3 years.

COMPOSITION

AmnioBind contains 400+ proteins, including collagens, fibrins, elastins, glucosaminoglycans and glycoconjugates.

HealthTech Wound Care, Inc.
healthtechwoundcare.com
833-381-2402

sales@worldreachhealth.com

Exclusively distributed by
World Reach Health, LLC

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Rolling Meadows, IL 60008
WorldReachHealth.com

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Manufactured By

HealthTech WOUND CARE

INTENDED USE

AmnioBind can be used as a protective wound covering as either a partial and full thickness acute and chronic wounds.

- Trauma Wounds
- Pressure Injuries
- Dehisced Wounds
- Wounds with Exposed Bone/Tendon
- Venous Leg Ulcers (VLUs)
- Diabetic Foot Ulcers (DFUs)

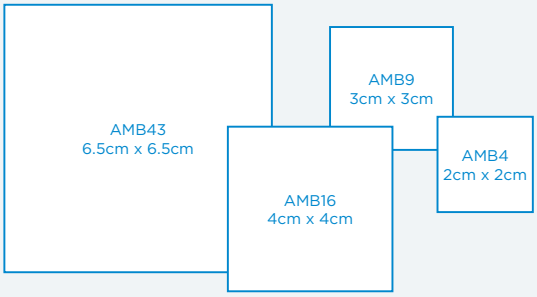
Can be used at the onset and for the duration of the wound, weekly or at the discretion of the treating physician.

APPLICATION

- Using aseptic technique, remove AmnioBind from the package; the product may be trimmed as necessary
- Place the AmnioBind patch onto the wound
- Assure AmnioBind is in intimate contact with the wound bed; the product can be hydrated once placed on the wound bed
- Adhere AmnioBind using preferred fixation method, then cover AmnioBind with a primary non-adherent dressing
- Apply secondary dressings specific to the wound type over the non-adherent layer, which should remain in place for up to one week

SIZE & STORAGE

- Available in a wide range of shapes and sizes
- Maintain at ambient temperature prior to patient application
- Do not freeze
- May be stored for up to 3 years at room temperature.



REIMBURSEMENT

- Medicare contractors cover AmnioBind for VLUs and DFUs†
- AmnioBind can be applied to, and billed for, other wound types
- Confirm coverage prior to treatment through our Benefits Program

†Consult with your LCD (local coverage determination) for the specific wound types covered.
VLU = venous leg ulcer; DFU = diabetic foot ulcer

AmnioBind billing	Q 4225

CPT codes

Site Preparation CPT‡	Application CPT codes‡
15002-15005	15271-15278

‡Subject to guidelines and approvals, please contact our billing team for further details

BILLING SUPPORT
REIMBURSEMENT@HEALTHTECHWC.COM

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healthtechwoundcare.com
833-381-2402
sales@worldreachhealth.com

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HealthTech WOUND CARE

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THE VALUE OF DERMABIND TL

INTRODUCTION TO DERMABIND TL™ ALLOGRAFT

The Value of DermaBind Triple Layer Placenta-based Allografts

a. We never separate the layers of our triple layer allograft.
b. The amnion, intermediate and chorion layer stay intact, and the membranes are not disrupted. the way a single or dual layer is when they are produced.

Thickest Allograft Option for Homologous Wound Covering

a. Single layer is 150 microns thin or 1/6 of a triple layer (very thin).
b. Dual Layer is 300-400 microns thin.
    i. A single layer that is folded back onto itself or amnion and chorion layers.
c. DermaBind Triple Layer is 1,000 microns/1mm thick (very thick).
    i. Good for layer covering, stitching and allowing coverage and handleability.

Advantages of Keeping All 3 Layers Together

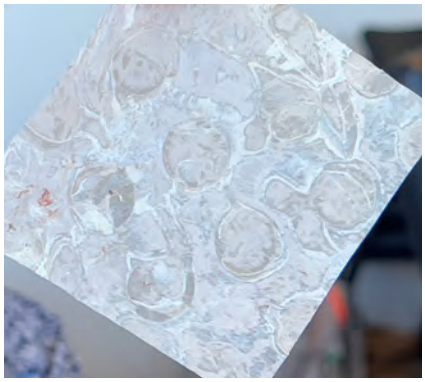
(Original state of amniotic layer of placenta)

a. By keeping all 3 layers together, this allows a very high abundance of proteins and cytokines exceeding those found in single or dual layer allografts.

Single Layer
150 Microns Thin

Dual Layer
300 - 400 Microns Thin

DermaBind (TL) Triple Layer
1,000 Microns Thick / 1 MM Thick



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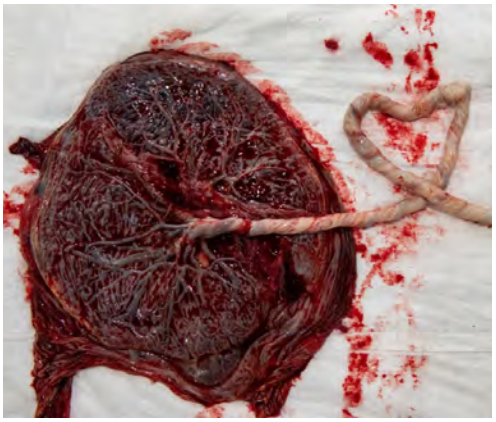
THE VALUE OF DERMABIND TL

AVERAGE SALES PRICE (ASP)

DermBind TL, ASP Price

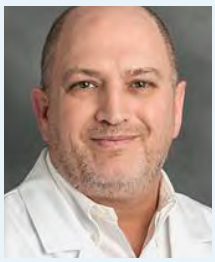
a. Current ASP for AmnioBind is $1450 per cm2.



FDA 361 DESIGNATED PRODUCT DERMABIND TL™ ALLOGRAFT

DermBind TL, a 361 Designated Product

a. We do not disrupt the natural state of the placental tissue in our manufacturing process and deliver an allograft option that is intact from its original state. The DermaBind TL allograft product is the closest to the original state of the biomaterial and the original intent of the 361-product description for minimal manipulation and homologous use. This is also reinforced by our manufacturing process.
    i. **Regulatory Considerations for Human Cells, Tissues, and Cellular and Tissue Based Products: Minimal Manipulation and Homologous Use**
    ii. 21 CFR Part 1271.10(a): https://www.fda.gov/media/109176/download



"The remarkable advantage I've discovered with the DermaBind TL Allograft is the elimination of the need for skin grafts, significantly expediting the healing process by tenfold or more. It's truly transformative. DermaBind TL is healing even better than the dual layer I have used in the past."

- David Fertel, DO

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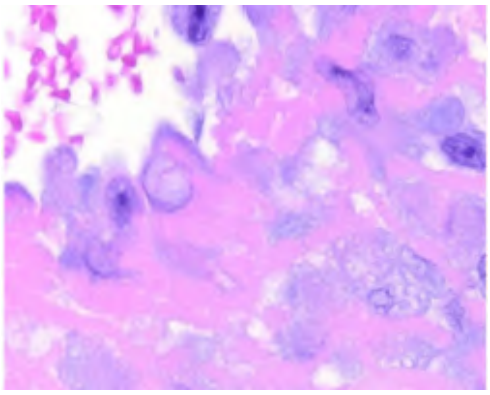
THE VALUE OF DERMABIND TL

OUR SUPERIOR MANUFACTURING PROCESS

Quality Assurance

a. DermaBind TL is manufactured under cGMP, cGTP, and ISO 13485 requirements and is processed from donors with normal, full-term pregnancies.
b. Each donor is carefully screened for comprehensive medical and social histories and is tested according to FDA requirements for Relevant Communicable Diseases.
c. Most placenta donors reside in Salt Lake City with higher statistics of healthier lifestyles and a very low failure rate



Cleaning Process

a. We don't use antibiotics or harsh chemicals.
b. Our aseptic process takes care of this in the cleaning stage.
c. No soaps or chemicals used to clean the product, therefore no need to remove these later.

Drying Process

a. By using an Evaporative Dryer, we are able to keep the structure of the membrane and provide space.
b. We fluff up the intermediate layer and dry it so the body can use the scaffolding and space for better use in the patient's treatment regimen.
    i. Other allografts do not have this space.
c. DermaBind TL is approved for a 3-year shelf life.

Radiation Process

a. The DermaBind radiation process is much less harsh due to our first steps for cleaning.
b. We use 17.5 kilogray, others can be known to use 25 kilogray.
c. The protein structure of the biomaterial can be negatively affected due to the use of that much radiation.

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U.S. FOOD & DRUG ADMINISTRATION

By Electronic Mail

January 5, 2023

Doug Schmid, PhD
HealthTech Wound Care, Inc.
615 Arapeen Drive, Suite 300
Salt Lake City, Utah 84108
dschmid@predictivebiotech.com

RE: Request for Recommendation for DermaBind™ TL Allograft

Dear Dr. Schmid:

This letter is in response to your inquiry provided to the Food and Drug Administration's Tissue Reference Group (TRG) on October 20, 2022. You are seeking a recommendation from the TRG whether DermaBind TL™ allograft, a placental membrane product, meets the criteria for regulation as a human cell, tissue, or cellular or tissue-based product (HCT/P) solely under section 361 of the Public Health Service (PHS) Act and 21 CFR part 1271.

Your submission describes processing of the placental membrane that includes rinsing, washing, cleaning, soaking, cutting, lyophilization, and sterilization using irradiation. The smallest product size is 3 cm x 3 cm and you explain that DermaBind TL™ is "for external wounds only," "for application directly to acute and chronic wounds" and is intended "for use as wound covering."

To be regulated solely under section 361 of the PHS Act and the regulations in part 1271, an HCT/P must satisfy all four criteria at 21 CFR 1271.10(a)[1]. Based on the description you provide of the processing steps and the minimum size of the product, DermaBind TL™, when intended as a "wound covering" for "acute and chronic wounds," appears to meet the criteria for regulation solely under section 361 of the PHS Act and the regulations in 21 CFR part 1271.

This recommendation applies solely to the DermaBind TL™ product described in your submission of October 20, 2022, when intended for use as a "wound covering" for "acute and chronic wounds." This recommendation does not apply to any other DermaBind branded products marketed by HealthTech Wound Care, Inc.

Please note that this recommendation is based on the information you provided. Any variation from

[1] The four criteria can be found at 21 CFR 1271.10(a), and, as applicable, see the following guidance documents: "Regulatory Considerations for Human Cell, Tissues, and Cellular and Tissue-Based Products: Minimal Manipulation and Homologous Use; Guidance for Industry and Food and Drug Administration Staff" dated July 2020; and, "Same Surgical Procedure Exception under 21 CFR 1271.15(b): Questions and Answers Regarding the Scope of the Exception; Guidance for Industry" dated November 2017.

what you describe in your request for recommendation to the TRG, including but not limited to changes in the processing or proposed use, may raise additional regulatory considerations that could impact the applicability of this recommendation. For example, an amniotic membrane product, when intended for wound healing and/or to reduce scarring and inflammation would not be considered a homologous use because wound healing and reduction of scarring and inflammation are not basic functions of amniotic membrane[2].

For questions regarding this response letter, please contact the Executive Secretary for the TRG at TissueReferenceGroup@fda.hhs.gov.

Sincerely,

Wilson Bryan -S

Digitally signed by Wilson Bryan -S
Date: 2022.12.30 14:13:46 -05'00'

Wilson W. Bryan, M.D.
Director
Office of Tissues and Advanced Therapies
Center for Biologics Evaluation and Research

James P. Bertram -S

Digitally signed by James P. Bertram -S
Date: 2023.01.05 09:19:50 -05'00'

James Bertram, Ph.D.
Director
Regulatory Policy and Combination Products Staff
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

[2] See Example 19-4 in "Regulatory Considerations for Human Cell, Tissues, and Cellular and Tissue-Based Products: Minimal Manipulation and Homologous Use; Guidance for Industry and Food and Drug Administration Staff" dated July 2020.

AmnioBind™ - HCP21090861EG3

Topic/Issue

Request to establish a new HCPCS Level II code to identify AmnioBind™.

Applicant's suggested language: Q4XXX "AmnioBind™ per sq cm."

Applicant's Summary

Predictive Biotechnology submitted a request to establish a new HCPCS Level II code to identify AmnioBind™. AmnioBind™ is a terminally sterilized, dehydrated, full thickness placental membrane (PM) allograft consisting of amnion, chorion, and the associated intermediate (spongy) layer (IL). Typically, following debridement, PM allografts are applied to the wound surface to provide a barrier to the environment. AmnioBind™ should always be maintained within closed packaging until just prior to administration. At the time of administration, the product can be removed (using proper sterile technique) by pulling the membrane out of the packaging. The allograft is intended to remain on the site for five to seven days. It is designed for application directly to acute and chronic wounds, is flexible, and is a conforming cover that adheres to complex anatomies. AmnioBind™ membrane is intended for use as a wound covering. This product is an allograft tissue intended for homologous use for the repair, reconstruction, and replacement of the recipient's tissue at the discretion of a physician.

Final Decision

Based on written feedback from the FDA's Tissue Reference Group (TRG), AmnioBind™, when intended for "repair, reconstruction and replacement of the recipient's tissue" and "as a covering", appears to meet the criteria for regulation solely under section 361 of the Public Health Service (PHS) Act and the regulations in 21 CFR part 1271. As a result of our review of the TRG's feedback, CMS has decided to:

Establish new HCPCS Level II code Q4225, "Amniobind, per square

centimeter" Effective: 4/1/2022

DermaBind TL™ - HCP230502KNQ6X

Topic/Issue

Request to revise existing HCPCS Level II code Q4225, “Amniobind, per square centimeter” to identify DermaBind TL™.

Applicant’s suggested language: Q4225, “AmnioBind or DermaBind TL per sq cm”

Summary of Applicant’s Submission

Health Tech Wound Care submitted a request to revise existing HCPCS Level II code Q4225, "AmnioBind, per square cm" to include the brand name DermaBind TL, for example, "DermaBind TL, per square cm." CMS established a new HCPCS Level II code Q4225, effective April 1, 2022, to identify a placental membrane product AmnioBind. Another product exists that has a similar name, properties, and function, necessitating a product name change to avoid confusion of the products. DermaBind TL™ is a terminally sterilized, dehydrated, full thickness placental membrane (PM) allograft consisting of amnion, chorion, and the associated intermediate (spongy) layer (IL). Typically, following debridement, PM allografts are applied to the wound surface to provide a barrier to the environment. DermaBind TL™ should always be maintained within closed packaging until just prior to administration. At the time of administration, the product can be removed (using proper sterile technique) by pulling the membrane out of the packaging. The allograft is intended to remain on the site for five to seven days. It is designed for application directly to acute and chronic wounds, is flexible, and is a conforming cover that adheres to complex anatomies. DermaBind TL™ membrane is intended for use as a wound covering at the discretion of a physician. Additionally, Q4225 identifies AmnioBind, per square cm. DermaBind TL™ is identical in every aspect to AmnioBind, except for the product name and manufacturer name. The name of the manufacturer has changed from Predictive Biotech to HealthTech Wound Care. DermaBind TL™ is manufactured in the same laboratory using the same equipment by the same technicians.

CMS Final HCPCS Coding Decision

After review of the Food and Drug Administration’s (FDA’s) Tissue Reference Group (TRG) letter submitted by the applicant, “Dermabind TL, when intended as a “wound covering” for “acute and chronic wounds,” appears to meet the criteria for regulation solely under section 361 of the Public Health Service (PHS) Act and the regulations in 21 CFR part 1271.”

As a result of our review of the TRG’s feedback, and in consideration of the applicant’s explanation that both products are manufactured in the same place, using the same equipment and staff, and are identical in every aspect with the exception of the product name and manufacturer name, CMS has decided to: Revise existing HCPCS Level II code Q4225, “Amniobind, per square centimeter” to instead read “Amniobind or dermabind tl, per square centimeter”.

WORLD REACH HEALTH

PRICING AND AGREEMENT OPTIONS

DERMABIND TL™ PRICING AND AGREEMENT OPTIONS

PRICING

Medicare Approved Pricing for all MACs for DermaBind TL

a. Pricing for DermaBind TL has been approved and is priced at $1,450 per square centimeter in all MAC regions.

AGREEMENT OPTIONS

Option 1 - Medicare Approved Discount Rate Agreement

a. 6% Medicare Approved Rate

Option 2 - Standard Agreement

a. 30% Discount

Option 3 - Marketing & Development Agreement

a. A fair market value discount based on provider collaboration.
b. Details upon further conversation.

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Healthtech
SOLUTIONS

To whom it may concern,

I am honored to have the opportunity to work with collaborative partners in our pursuit to change the wound care market. At HealthTech Wound Care, and our family of companies, we strive to manufacture the best products, educate caregivers, educate our sales and marketing partners, but also educate the public. Everyone can play a role in improving the treatment and outcomes of those who need our help. Whether we are developing in-house-inspired ideas or creating strategic partnerships, we are committed to providing the highest level of excellence to our customers, B2B partners, and our shareholders through innovation, vertical integration, and comprehensive value-added services.

We are also partnering with physicians who share our vision and they are providing us with clinical data to ensure we have the best patient outcomes. We recognize that first-hand data is critical and needed to continuously improve our products.

Additionally, we strive to partner with the best sales and marketing groups, as they are our representation in the field. We work collectively to build out educational material and ensure that all of our team members are involved in the education training courses. We are also building out educational courses for the caretakers to further expand our outreach.

I would personally like to extend an invitation to have you and your team come to Salt Lake City and tour our facilities. There is no better way to see who we are than seeing our team in action. You will have the opportunity to meet our management staff and hear, from their perspectives, how we are challenging our teams to continuously seek improvements and better outcomes. We know that our products change people's lives and we do not take that lightly. We want to improve more lives and continue to reach more of those in need.

Please do not hesitate to reach out to me with any questions, comments, or suggestions. We are all a team and the only way to accomplish our mission is to work together.

Thank you for allowing me to share my team and our efforts.

Respectfully,

Jelena Olmstead
CEO

WORLD REACH HEALTH

Effective 1/1/23

New Customer On-Boarding Form

Agent: Kimberley O'Sullivan 781-366-4600 KOSMDConsult@gmail.com

CUSTOMER NAME: _____ **D/B/A** _____

ENTITY TYPE: _____ **CORP.** _____ **LLC** _____ **Partnership** _____ **Sole Proprietorship**

STATE OF INCORPORATION / ORGANIZATION: _____ **YEAR ESTABLISHED** _____

BILLING ADDRESS: _____

CITY: _____ **STATE**: _____ **ZIP**: _____

OWNER/PRINCIPAL: _____ **TITLE:** _____

PHONE: _____ **FAX**: _____

EMAIL: _____ **WEB:** _____

ACCOUNTS PAYABLE CONTACT: _____

PHONE: _____ **EMAIL**: _____

FEIN: _____ **DUNS**: _____ **CAGE CODE:** _____

HOW DO YOU BILL? _____ **Individual NPI #** _____ **Group NPI #**

CLAIMS PROCESS INFORMATION

CONTACT NAME: _____ **PHONE:** _____ **EMAIL:** _____

TAX EXEMPT: _____ YES ____ NO

IF TAX EXEMPT, PLEASE PROVIDE RESALE CERTIFICATE AND/OR TAX-EXEMPT DOCUMENTS

TERMS OF SALE: Customer Agrees to the Company's standard Terms and Conditions of Sale, as posted on its website at www.WorldReachHealth.com, and as may be amended from time to time.

CREDIT: Customers may apply for credit terms with World Reach Health by completing a credit application.

Send THIS COMPLETED FORM TO kosmdconsult@gmail.com .

_____ _____ _____

Signature Printed Name & Title Date

WORLD REACH HEALTH

Sales Rep: Kimberley OSullivan 781-366-4600 KOSMDConsult@gmail.com

FULFILLMENT PROGRAM

Date	(the **"Effective Date"**)
Seller	World Reach Health, LLC (**"Seller"**)
Seller's Address	3501 W. Algonquin Rd, Suite 135, Rolling Meadows, IL 60008
Provider	(**"Purchaser"**)
Provider's Address	
Provider's Contact Person	

Purchaser desires to purchase from Seller, and Seller has agreed to sell to Purchaser human cell and tissue products, subject to Seller's terms and conditions of sale (the **"Terms"**), which Purchaser acknowledges having received a copy, and the terms and conditions contained herein.

Now, therefor, the parties agree as follows:

1. **Product Prices**. For the purpose of this Agreement, **"Products"** shall mean the human cell and tissue products offered by Seller, which are more specifically itemized in **Schedule "A,"** which is attached hereto, and may be amended from time to time. The unit price per product (the **"Unit Price"**) is the price stated for each Product in Schedule A.

2. **Insurance Verification**. Purchaser agrees to utilize Seller's approved insurance verification request form (the **"IVR Form"**) prior to ordering and using the Products.

3. **Order Fulfillment**. After Purchaser submits the IVR Form to Seller and Purchaser receives confirmation of a patient's benefits, Purchaser will order the Products from Seller. Seller will issue one (1) invoice per Product on or about the date the Products are shipped to Purchaser. Each invoice shall be subject to the Terms, which Purchaser acknowledges having received, reviewed and agreed upon. Each Product order shall be timely shipped via second-day delivery. Seller shall include shipment / tracking information from the carrier on each invoice.

4. **Product Usage**. Upon Purchaser's receipt of the Products, Purchaser will treat each patient as medically necessary. The parties acknowledge that use of any Products shall be solely at the discretion of the treating provider, pursuant to their professional medical judgment.

5. **Invoices & Payments**. Purchaser shall make all outstanding payments within thirty (30) days of the date of each invoice, unless otherwise noted on each invoice.

6. **Miscellaneous**. This Agreement, and the Terms, contain the entire agreement between the parties. This Agreement, and the Terms, shall be governed by Illinois law. This Agreement and the Terms may only be amended by written agreement between the parties.

Executed as of the Effective Date

SELLER	**PURCHASER**
_____	_____
World Reach Health, LLC	
By: Jim Pesoli	By:
Its: Authorized Signatory	Its: Authorized Signatory

Sales Rep: Kimberley OSullivan 781-366-4600 KOSMDConsult@gmail.com

***FAX THIS COMPLETED FORM TO 847-463-0554 OR EMAIL SALES@WORLDREACHHEALTH.COM**

WORLD REACH HEALTH

AMNIOBIND ALLOGRAFT ORDER FORM

Email completed form to sales@worldreachhealth.com

ACCOUNT REPRESENTATIVE

REP NAME: Kimberley O'Sullivan DATE: _____

REP EMAIL: KOSMDConsult@gmail.com CELL: 781-366-4600

PROVIDER'S BILLING INFORMATION

CLINIC NAME: _____

PHYSICIAN NAME: _____

NPI #: _____

BILLING ADDRESS: _____

CONTACT PERSON: _____

EMAIL: _____

PHONE: _____

CHECK IF SIGNATURE IS ON FILE

SHIPPING INFORMATION

CHECK IF SAME AS BILLING INFO

CLINIC NAME: _____

SHIPPING ADDRESS: _____

_____

CONTACT PERSON: _____

EMAIL: _____

PHONE: _____

OVERNIGHT SHIPPING REQUESTED

AmnioBind Allograft	Total CM^2	Sizing & Pricing	
SIZE	TOTAL CM^2	PRICE PER CM^2	UNIT PRICE
2.0CM X 2.0CM	$4CM^2$	$1,450	$5,800
3.0CM X 3.0CM	$9CM^2$	$1,450	$13,050
4.0CM X 4.0CM	$16CM^2$	$1,450	$23,200
6.5CM X 6.5CM	$43CM^2$	$1,450	$62,350

ORDERING INSTRUCTIONS

- Email completed form to sales@worldreachhealth.com
- Orders received prior to 2pm MST may be eligible for same day shipping
- Orders will be shipped via ground transportation (included), allow 2 days for delivery
- If expedited (overnight) shipping is requested additional fees may apply
- Available products will be confirmed by email and ship within one business day

				Allograft Size & Quantity					
#	Patient Name	Wound Location	IVR Approval #	2.0 x 2.0	3.0 x 3.0	4.0 x 4.0	6.5 x 6.5	Total CM^2	Week #
			TOTAL						

TOTAL SQCM

INTERNAL USE ONLY

DATE ORDERED

World Reach Health, LLC
Tel: 847-220-4664
Fax: 847-463-0554
Email: sales@worldreachhealth.com
Web: www.WorldReachHealth.com
3501 W. Algonquin Rd, Suite 135
Rolling Meadows, IL 60008

WORLD REACH HEALTH

HealthTech Wound Care Patient Support Program Patient Insurance Verification Form

3 Ways to Submit IVR Request Form:

- ☐ **Fax completed form to: 833.717.2940**
- ☐ **Upload this form via your dedicated portal**
- ☐ **Email Form: reimbursement@healthtechwc.com**

Account Representative Name: **Kimberley O'Sullivan**

Contact Email: **KOSMDConsult@gmail.com**

Phone Number: **781-366-4600**

☐ **AmnioBind - Q4225** ☐ **DermaBind SL - Q4284**

TYPE OF INSURANCE VERIFICATION REQUEST

Please select one: ☐ New Application ☐ Prior Authorization ☐ Additional Applications ☐ Re-verification ☐ Appeal/Denial Request (Please provide EOBs and denial documentaion.)

PATIENT INFORMATION:

*Please submit copies of insurance cards (front & back) and patient demographics sheet. *Provide Medical Record Number (MRN) if available.*

Patient Name:			DOB:
Address:			MRN:
City:	State:		Zip Code:
Primary Ins:	Ins ID#:	Group #:	Ins. Phone:
Secondary Ins:	Ins ID#:	Group #:	Ins. Phone:
Is patient currently in a surgical global period? ☐ Yes ☐ No	If yes, what is the CPT surgery code?		Surgery Date?
Is patient currently residing in a nursing home or any in-patient facility? ☐ Yes ☐ No	*Reminder: Q Codes not separately payable while patient under part A episode of care.*		

PROVIDER INFORMATION:

Place of Service: ☐ Physician Office (11) ☐ Home (POS 12) ☐ Nursing Facility (POS 32) ☐ Ambulatory Surgical Center (24) ☐ HOPD (22) ☐ Other: Please List Place of Service (CAH, SNF): _____

Rendering Physician Name:		
NPI:	TIN:	Medicare PTAN:
Address:		Provider Phone:
City:	State:	Provider Fax:
Primary Contact Person:		Contact Phone:
Contact Email Address:		Contact Fax:

FACILITY INFORMATION:

Facility Name:	Facility Phone:	Facility Fax:
Facility Address:		
Facility NPI:	Facility TIN:	Medicare PTAN (Group):
Primary Contact Person:		Contact Phone:
Contact Email Address:		Contact Fax:

PROCEDURE INFORMATION:

*Please attach all supporting clinical documentation such as treatment plan, progress notes, and LOMN.

Anticipated Treatment Start Date:	Wound Location:	Wound Size:
Diagnosis ICD-10 Codes:		
☐ Diabetic Foot Ulcer ☐ Venous Leg Ulcer ☐ Lower Extremity Chronic Ulcer ☐ Other: _____		
Number of Grafts:	Size of Initial Graft (in sq.cm):	
Additional Clinical Comments:		
Physician Signature:		☐ Physician Signature on file

The signature above certifies that the physician has the necessary patient authorization to release the medical and/or patient information to COMPANY, its contractors and the patient's health insurance company as necessary to research insurance coverage and determine benefits related to COMPANY products.
COVERAGE, REIMBURSEMENT AND/OR BENEFIT VERIFICATION FOR ANY PRODUCT OR PROCEDURE CANNOT BE GUARANTEED, AND THE COMPANY REIMBURSEMENT HOTLINE AND COMPANY DISCLAIM LIABILITY FOR PAYMENT OR NONPAYMENT OF ANY CLAIMS, BENEFITS OR COSTS. THIRD-PARTY PAYMENT FOR MEDICAL PRODUCTS AND SERVICES IS AFFECTED BY NUMEROUS FACTORS. IT IS THE PROVIDER'S RESPONSIBILITY TO DETERMINE AND SUBMIT APPROPRIATE CODES, CHARGES AND MODIFIERS FOR SERVICES RENDERED.

ABOUT THIS GUIDE

World Reach Health and it's affiliates proclaim that the below information is presented only for the purposes of illustrative suggestion and is not intended to provide coding, reimbursement, treatment, or legal advice. The payment amounts mentioned in this document represent national unadjusted averages and do not incorporate the 2% sequestration or any other patient responsibilities. The coding provided here is strictly intended for informational purposes and should not be interpreted as a declaration, assurance, or guarantee of their accuracy or reimbursement. Coding practices, may differ based on the site of service, patient's condition, services rendered, instructions from local Carriers and Fiscal Intermediaries, along with other factors. Coding requirements are sometimes subject to modifications at any given time, such that it is advisable for regularly consultation from your local payer for the most current information.

REIMBURSEMENT SERVICES & SUPPORT
reimbursement@healthtech.com

DIAGNOSIS CODES (ICD-10 CODES)

DermaBind™ TL/DermaBind™ SL are dehydrated, intact placental membranes that is processed and distributed in accordance with FDA requirements for Human Cellular and Tissue-based Products (HCT/P) (21 CFR Part 1271). Caution: Federal Law restricts this product to sale by or on the order of a licensed medical professional, not for veterinary use.

DermaBind™ TL/DermaBind™ SL are wound covering for patients that suffer from a variety type of acute and chronic wounds including, but not limited to, diabetic ulcers, pressure ulcers, venous stasis ulcers, and burns.

We recommend reviewing your Local Coverage Determination (LCD) for approved uses.

PRODUCT CODE (HCPCS CODE)

Q4225

HCPCS CODE

Description:
DermaBind™ TL per square centimeter.

Medicare Payment Rate:
Priced by contractor.

This product is an allograft tissue intended for homologous use for the repair, reconstruction, and replacement of the recipient's tissue at the discretion of a physician.

Size	Area	Billing Units
2.0 x 2.0 cm	4.00 cm^2	4
3.0 x 3.0 cm	9.00 cm^2	9
4.0 x 4.0 cm	16.00 cm^2	16
6.5 x 6.5 cm	42.25 cm^2	43

HCPCS codes not listed on the National Medicare Part B ASP file* are priced individually by Medicare Administrative Contractor (MAC).

For information specific to your MAC, please contact the Medical Reimbursement Hotline, 833-381-2402 (option 2).

*Medicare fee for service part B drug average sale price list.

Q4284

HCPCS CODE

Description:
DermaBind™ SL, per square centimeter.

Medicare Payment Rate:
Priced by contractor.

This product is an allograft tissue intended for homologous use for the repair, reconstruction, and replacement of the recipient's tissue at the discretion of a physician.

Size	Area	Billing Units
2.0 x 2.0 cm	4.00 cm^2	4
3.0 x 3.0 cm	9.00 cm^2	9
4.0 x 4.0 cm	16.00 cm^2	16
6.5 x 6.5 cm	42.25 cm^2	43

HCPCS codes not listed on the National Medicare Part B ASP file* are priced individually by Medicare Administrative Contractor (MAC).

For information specific to your MAC, please contact the Medical Reimursement Hotline, 833-381-2402 (option 2).

*Medicare fee for service part B drug average sale price list.

Trunks, Arms & Legs

Less than or equal to 100 cm^2

15271 + **15272**

First 25 cm^2

*Each additional 25 cm^2

Greater than or equal to 100 cm^2

15273 + **15274**

First 100 cm^2

*Each additional 100 cm^2

Face, Scalp, Hands & Feet

Less than or equal to 100 cm^2

15275 + **15276**

First 25 cm^2

*Each additional 25 cm^2

Greater than or equal to 100 cm^2

15277 + **15278**

First 100 cm^2

*Each additional 100 cm^2

- Verify the size of AmnioBind® / DermaBind™ SL applied and bill the appropriate number of units. AmnioBind® / DermaBind™ SL is considered a single use product; always bill for the entire piece.
- Understand the CPT® code descriptors: look at total surface area and anatomical location.
- Review add-on CPT® codes for larger wounds (between 25-100 cm2).
- Verify your billed charge for AmnioBind® / DermaBind™ SL. Review applicable allowables and your cost. Determine your charge using the methodology you use for other products/services.

APPLICATION CODES

CPT Code	CPT Description	Medicare National Average payment 2023 Non - facility (Office)	Medicare National Average payment 2023 facility
15271	Application of wound covering graft to trunk, arms, legs, total wound surface area up to 100 sq. cm; first 25 sq. cm or less wound surface area.	$155.88	$83.70
+ 15272	Application of wound covering graft to trunk, arms, legs, total wound surface area up to 100 sq. cm; each additional 25 sq. cm wound surface area, or part thereof (List separately in addition to code for primary)	$24.40	$16.61
15273	Application of wound covering graft to trunk, arms, legs, total wound surface area greater than or equal to 100 sq. cm; first 100 sq. cm wound surface area, or 1% of body area of infants and children.	$315.83	$196.55
+ 15274	Application of wound covering graft to trunk, arms, legs, total wound surface area greater than or equal to 100 sq. cm; each additional 100 sq. cm 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)	$84.04	$45.07
15275	Application of wound covering 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 wound surface area.	$160.63	$93.19
+ 15276	Application of wound covering 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; each additional 25 sq. cm wound surface area, or part thereof (List separately in addition to code for primary procedure)	$32.87	$25.08
15277	Application of wound covering 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 wound surface area, or 1% of body area of infants and children.	$350.39	$225.35
+ 15278	Application of wound covering 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; each additional 100 sq. cm 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.)	$96.92	$55.91

*"+" indicates add-on code (AOC). An add-on code (AOC) is a proedure code that describes a service that is performed in conjunction with the primary service by the same practitioner. Add-on codes are rarely eligible for payment unless they are reported with a valid primary procedure code on the same date of service.

Add-on codes are identified throughout the CPT manual by a "+," and their descriptor will contain some variation of the phrase "report in addition to code for primary procedure". You can find a complete list of add-on codes in Appendix D of the CPT manual.

*MAC Regions by State

MAC	MAC Jurisdiction	Processes Part A & Part B Claims for the following states/territories:
CGS Administrators, LLC	15	Kentucky, Ohio
First Coast Service Options, Inc.	N	Florida, Puerto Rico, U.S. Virgin Islands
National Government Services, Inc.	6	Illinois, Minnesota, Wisconsin
National Government Services, Inc.	K	Connecticut, New York, Maine, Massachusetts, New Hampshire, Rhode Island, Vermont
Noridian Healthcare Solutions, LLC	E	California, Hawaii, Nevada, American Samoa, Guam, Northern Mariana Islands
Noridian Healthcare Solutions, LLC	F	Alaska, Arizona, Idaho, Montana, North Dakota, Oregon, South Dakota, Utah, Washington, Wyoming
Novitas Solutions, Inc.	H	Arkansas, Colorado, New Mexico, Oklahoma, Texas, Louisiana, Mississippi
Novitas Solutions, Inc.	L	Delaware, District of Columbia, Maryland, New Jersey, Pennsylvania (includes Part B for counties of Arlington and Fairfax in Virginia and the city of Alexandria in Virginia)
Palmetto GBA, LLC	J	Alabama, Georgia, Tennessee
Palmetto GBA, LLC	M	North Carolina, South Carolina, Virginia, West Virginia (excludes Part B for the counties of Arlington and Fairfax in Virginia and the city of Alexandria in Virginia)
Wisconsin Physicians Service Government Health Administrators	5	Iowa, Kansas, Missouri, Nebraska
Wisconsin Physicians Service Government Health Administrators	8	Indiana, Michigan

*Source: https://www.cms.gov/files/document/macs-state03282023pdf.pdf

DOCUMENTATION CHECKLIST

IMPORTANT: The following guidelines are limited and suggested based on general documentation practices. For specific information, please reference your Local Coverage Determination (LCD), Product Instructions for use (IFU), and CMS medically necessary guidelines, for comprehensive criteria.

- ◯ Baseline measurements of the wound immediately prior to initiation of treatment (size, location, stage, duration)
- ◯ Type(s) of conservative treatment that failed to induce significant healing
- ◯ Presence or absence of infection and treatment provided/response (if applicable)
- ◯ Adequate application of the underlying disease contributing to the ulcer
- ◯ Adequate blood flow
- ◯ Adequate glucose control (diabetic patients)
- ◯ Clean wound bed, free of exudate or necrotic tissue
- ◯ Note AmnioBind®/ DermaBind™ SL by name/descriptor and provide lot number
- ◯ Wound description prior to and after DermaBind™ SL/DL wound application
- ◯ Application number and improvement since last treatment
- ◯ Amount of AmnioBind®/ DermaBind™ SL utilized and amount discarded (if applicable) (Tissue Utilization Record)
- ◯ Appropriate wound dressing Utilization Record)
- ◯ Appropriate offloading implimented (diabetic foot ulcer)

WORLD REACH HEALTH

NEW CUSTOMER QUESTIONNAIRE

NEW CUSTOMER QUESTIONNAIRE

Sales Rep: Kimberley O'Sullivan. 781-366-4600. KOSMDConsult@gmail.com

CLINIC NAME: _____ EMAIL: _____

PHYSICIAN NAME: _____ PHONE: _____

Approximately how many patients per month will be eligible for allograft service and treatment?

Patients per month

Would you prefer to have us train your billing team or would you like to meet our billing service reference?

Have our team train your billing team **Meet our Billing Service Reference**

Would you recommend products or services to your colleagues?

YES **NO**

Would you be interested in taking a tour of our Allograft laboratory in Salt lake City Utah ?

YES **NO**

Would you be willing to be on video or podcast as a testimonial or educational discussion in the future on the topic of allografts and wound care?

YES **NO**

Will you allow World Reach Health materials such as trifolds, one sheets, posters, 6' banner, in your offices for patient education?

YES **NO**

Thank you for your time and input

WORLD REACH HEALTH

WORLD REACH HEALTH SUPPORT INFORMATION

SUPPORT INFORMATION

1. **Your Local Representatives**
   a. **Kimberley O'Sullivan**
      i. **781-366-4600**
      ii. **KOSMDConsult@gmail.com**

2. **HealthTech Wound Care Customer Service**
   a. Tel: 833-831-2402

3. **Billing Support**
   a. reimbursement@healthtechwc.com

4. **Questions on Oredering Allografts**
   a. Contact Local Sales Rep at:
      i. sales@worldreachhealth.com
      ii. Tel: 847-220-4664

5. **IVR Support**
   a. 3 Ways to Submit IVR Request Form
      i. Fax completed form to: Tel: 833-717-2940
      ii. Upload to your dedicated portal
      iii. Email form to: reimbursement@healthtechwc.com

6. **Allograft Storage Information**
   a. Maintain at ambient temperature prior to patient application
   b. Do not freeze
   c. May be stored for up to 3 years at room temperature

7. **Allograft Manufacturer**
   a. HealthTech Wound Care, Inc.
   b. healthtechwoundcare.com
   c. Tel: 833-381-2402