ZENITH
AMNIOTIC MEMBRANE

Zenith™

Amniotic Membrane Allograft

2023
Reimbursement Guide

Distributed by:

LEGACY MEDICAL
CONSULTANTS

Reimbursement Disclaimer

This information is for educational/informational purposes only and should not be construed as authoritative. The information presented here is based upon publicly available source information. Codes and values are subject to frequent change without notice. The entity billing Medicare and/or third-party payors is solely responsible for the accuracy of the codes assigned to the services or items in the medical record. When making coding decisions, we encourage you to seek input from the AMA, relevant medical societies, CMS, your local Medicare Administrative Contractor, and other health plans to which you submit claims. Items and services that are billed to payors must be medically necessary and supported by appropriate documentation. It is important to remember that while a code may exist describing certain procedures and/or technologies, it does not guarantee payment by payors.

General Reimbursement and Coding

Reimbursement and coverage eligibility for the use of Zenith™ Amniotic Membrane and associated procedures varies by Medicare and Private Payers. Coverage policies, prior authorizations, contract terms, billing edits, and site of service influence reimbursement.

Place of Service (POS) Codes

POS codes are 2-digit numbers included on health care professional claims to indicate the setting in which a service was provided. The Centers for Medicare and Medicaid Services (CMS) maintain POS codes used throughout the healthcare industry. Listed below are POS and descriptions that typically apply to our products. These codes should be used on professional claims to specify the entity where service(s) were rendered. Check with individual payors for reimbursement policies regarding these codes.

Place of Service Code 11 – Office

(Location other than a hospital, skilled nursing facility (SNF), military treatment facility, community health center, State or Local public health clinic, or intermediate care facility (ICF), where the health professional routinely provides health examinations, diagnosis, and treatment of illness or injury on an ambulatory basis).

Place of Service Code 12 – Home

(Location, other than a hospital or other facility, where the patient receives care in a private residence.)

Place of Service Code 32 – Nursing Facility

A facility which primarily provides to residents skilled nursing care and related services for the rehabilitation of injured, disabled, or sick persons, or, on a regular basis, health-related care services above the level of custodial care to other than individuals with intellectual disabilities.)

General Reimbursement and Coding

CPT® Coding

The Current Procedural Terminology (CPT) code set describes medical, surgical, and diagnostic services and is designed to communicate uniform information about medical services and procedures among physicians, coders, patients, accreditation organizations, and payers for administrative, financial, and analytical purposes.

CPT®	DESCRIPTIONS FOR APPLICATION OF SKIN SUBSTITUTES
15271	Application of skin substitute graft to trunk, arms, legs, total wound surface area up to 100 sq cm; first 25 sq cm or less wound surface area
+15272	Each additional 25 sq. cm up to 100 sq. cm wound surface area, or part thereof. List separately in addition to code 15271 for primary procedure.
15273	Application of skin substitute 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
+15274	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 15273 for primary procedure.
15275	Application of 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 so. cm; first 25 cm or less wound surface area
+15276	Each additional 25 sq. cm wound surface area, or part thereof. List separately in addition to code 15275 for primary procedure.
15277	Application of 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 wound surface area, or 1% of body area of infants
+15278	Each additional 100 sq. cm wound surface area, or part thereof. List separately in addition to code 15277 for primary procedure.

CPT® Codes 15271-15278:

- Billing Units = 1 unit per service for CPT® 15271, 15273, 15275 and 15277 (daily limitations apply)
- Add-on codes 15272, 15274, 15276 and 15278 are billed as 1 unit for each additional amount of graft material as specified; either each additional 25 cm2 or 100 cm2 applied

Add-on Codes: The + symbol signifies an add-on code. An add-on code cannot be used alone but must be billed with the initial code above it. Please check the CPT® 2022 coding book for further instructions.

Modifiers: Check to see if modifiers are required and/or the CPT® codes used.
Common modifiers may include:

- JC: skin substitute used as a graft
- KX: requirements in the medical policy have been met

General Reimbursement and Coding

ICD-10© Codes

It is recommended that providers select the most specific primary and secondary diagnosis codes to accurately describe the reason the wound is not healing properly, and codes that indicate the wound is chronic and describe the location, severity, and laterality (for lower extremity ulcers).

Example of specific Diabetic Foot Ulcers (DFUs) codes:

- Primary diagnosis: E11.621, type 2 diabetes mellitus with a foot ulcer
- Secondary diagnosis: L97.522, non-pressure chronic ulcer of other part of left foot with fat layer exposed

Example of specific Venous Leg Ulcers (VLUs) codes:

- Primary diagnosis: I87.312, chronic venous hypertension (idiopathic) with ulcer of left lower extremity
- Secondary diagnosis: L97.222, non-pressure chronic ulcer of left calf with fat layer exposed

Important Billing Instructions

Zenith Amniotic Membrane (Q4253) is included on the Medicare Part B Average Sales Price (ASP) Drug Pricing File published quarterly by the Centers for Medicare and Medicaid Services (CMS)

- Average Sales Price information is published quarterly by the Centers for Medicare and Medicaid Services (CMS) in the ASP Medicare Part B Drug Pricing File or Not Otherwise Classified (NOC) Pricing File. Providers are encouraged to review the ASP Pricing files posted quarterly by CMS and listed by HCPCS on CMS.gov for updates.
- Payment allowance limits that are not included in the ASP Medicare Part B Drug Pricing File or Not Otherwise Classified (NOC) Pricing File, are based on the published Wholesale Acquisition Cost (WAC) or invoice pricing. In determining the payment limit based on WAC, the contractors follow the methodology specified in Publication. 100-04, Chapter 17, Drugs and Biologicals, for calculating the Average Wholesale Price (AWP), but substitute WAC for AWP.
- Providers are encouraged to check with their local MACs for information on established rates
- Providers are also encouraged to check with payers to determine if an invoice is required to be submitted with the claim and/or in Box 19 of the CMS-1500 claim form.
- Providers should check with local payers regarding appropriate use of modifiers.

Physicians should report all surgical and medical services performed, and are responsible for determining which CPT® code(s) appropriately.

Procedure Codes for Application of Skin Graft Substitutes References

2023 MEDICARE NATIONAL AVERAGE PAYMENT

CPT® CODE[2]	DESCRIPTION	PHYSICIAN OFFICE[3]	PHYSICIAN SERVICES IN HOPPS/ASC
15271	App of skin sub to trunk, arms, legs, up to 100 sq. cm; 15 25 sq. cm	$152.08	$81.66
+15272	Each additional 25 sq. cm	$23.80	$16.20
15273	App of skin sub to trunk, arms, legs to > 100 sq. cm, 1st 100 sq. cm	$308.13	$191.75
+15274	Each additional 100 sq. cm	$81.99	$43.97
15275	App of skin sub to face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, multiple digits up to 100 sq. cm; 1st 25 sq. cm	$156.71	$90.92
+15276	Each additional 25 sq. cm	$32.07	$24.46
15277	App of skin sub to face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, multiple digits 100 sq. cm	$341.85	$219.85
+15278	Each additional 25 sq. cm	$94.55	$54.55

Coinsurance/Deductibles:

As with all products and services paid for under Medicare Parts A & B, Medicare will reimburse 80 percent of the allowable amount. The patient, or secondary/supplemental plan, is responsible for the remaining 20 percent coinsurance amount. The appropriate annual deductibles also apply.

Sequestration:

Since April 1, 2013, all Medicare claims with a date-of-service on or after April 1, 2013 are subjected to a 2 percent sequestration amount, which remains in effect in the U.S. budget until 2022. Please note, the 2 percent is deducted from the 80 percent allowable amount paid by Medicare and not the coinsurance amount.

Geographic Practice Cost Index (GPCI):

The Medicare physician fee schedule amounts are adjusted to reflect the variation in practice costs from area to area. A GPCI has been established for every Medicare payment locality based on the RVUs for work, practice expense, and malpractice. The GPCIs are applied in the calculation of a fee schedule payment amount by multiplying the RVU for each component times the GPCI for that component.

Procedure coding should be based upon medical necessity, procedures and supplies provided to the patient. Coding and reimbursement information is provided for educational purposes and does not assure coverage of the specific item or service in a given case. Stability Biologics makes no guarantee of coverage or reimbursement of fees. These payment rates are nationally unadjusted average amounts and do not account for differences in payment due to geographic variation. Contact your local Medicare Administrative Contractor (MAC) or CMS for specific information as payment rates listed are subject to change. To the extent that you submit cost information to Medicare, Medicaid or any other reimbursement program to support claims for services or items, you are obligated to accurately report the actual price paid for such items, including any subsequent adjustments. CPT five-digit numeric codes, descriptions, and numeric modifiers only are Copyright AMA. (Updated January 2022)

Common ICD-10-CM Diagnosis Code Reference

The following chart provides some of the common diagnoses and ICD-10-CM codes that may require skin substitute grafts as a treatment option. This partial list is provided only for reference and does not represent any particular case or suggested treatment. Not all options are presented here, and the provider is always responsible for the assignment of the actual diagnosis codes as documented in the medical record.

CODE	DESCRIPTION (These are common codes, not an exhaustive list.)
DIABETIC ULCER CODES	
E08.621	Diabetes mellitus due to underlying condition with foot ulcer
E08.622	Diabetes mellitus due to underlying condition with other skin ulcer
E09.621	Drug or chemical induced diabetes mellitus with foot ulcer
E09.622	Drug or chemical induced diabetes mellitus with other skin ulcer
E10.621	Type 1 diabetes mellitus with foot ulcer
E10.622	Type 1 diabetes mellitus with other skin ulcer
E11.621	Type 2 diabetes mellitus with foot ulcer
E11.622	Type 2 diabetes mellitus with other skin ulcer
E13.621	Other specified diabetes mellitus with foot ulcer
E13.622	Other specified diabetes mellitus with other skin ulcer
VARICOSE VEINS OF LOWER EXTREMITY	
I83.012	Varicose veins of right lower extremity with ulcer of calf
I83.013	Varicose veins of right lower extremity with ulcer of ankle
I83.014	Varicose veins of right lower extremity with ulcer of heel and midfoot
I83.015	Varicose veins of right lower extremity with ulcer other part of foot
I83.018	Varicose veins of right lower extremity with ulcer other part of lower leg
I83.022	Varicose veins of left lower extremity with ulcer of calf
I83.023	Varicose veins of left lower extremity with ulcer of ankle
I83.024	Varicose veins of left lower extremity with ulcer of heel and midfoot
I83.025	Varicose veins of left lower extremity with ulcer other part of foot
I83.028	Varicose veins of left lower extremity with ulcer other part of lower leg
POSTTHROMBOTIC SYNDROME LOWER EXTREMITY	
I87.011	Postthrombotic syndrome with ulcer of right lower extremity
I87.012	Postthrombotic syndrome with ulcer of left lower extremity
I87.013	Postthrombotic syndrome with ulcer of bilateral lower extremity
CHRONIC VENOUS HYPERTENSION OF LOWER EXTREMITY	
I87.311	Chronic venous hypertension (idiopathic) with ulcer of right lower extremity
I87.312	Chronic venous hypertension (idiopathic) with ulcer of left lower extremity
I87.313	Chronic venous hypertension (idiopathic) with ulcer of bilateral lower extremity

Common ICD-10-CM Diagnosis Code Reference

(Continued)

CODE	DESCRIPTION (These are common codes, not an exhaustive list.)
NON-PRESSURE CHRONIC ULCER OF LOWER LIMB	
L97.311	Non-pressure chronic ulcer of right ankle limited to breakdown of skin
L97.312	Non-pressure chronic ulcer of right ankle with fat layer exposed
L97.321	Non-pressure chronic ulcer of left ankle limited to breakdown of skin
L97.322	Non-pressure chronic ulcer of left ankle with fat layer exposed
L97.411	Non-pressure chronic ulcer of right heel and midfoot limited to breakdown of skin
L97.412	Non-pressure chronic ulcer of right heel and midfoot with fat layer exposed
L97.421	Non-pressure chronic ulcer of left heel and midfoot limited to breakdown of skin
L97.422	Non-pressure chronic ulcer of left heel and midfoot with fat layer exposed
L97.511	Non-pressure chronic ulcer of other part of right foot limited to breakdown of skin
L97.512	Non-pressure chronic ulcer of other part of right foot with fat layer exposed
L97.521	Non-pressure chronic ulcer of other part of left foot limited to breakdown of skin
L97.522	Non-pressure chronic ulcer of other part of left foot with fat layer exposed
L97.811	Non-pressure chronic ulcer of other part of right lower leg limited to breakdown of skin
L97.812	Non-pressure chronic ulcer of other part of right lower leg with fat layer exposed
L97.821	Non-pressure chronic ulcer of other part of left lower leg limited to breakdown of skin
L97.822	Non-pressure chronic ulcer of other part of left lower leg with fat layer exposed
L97.211	Non-pressure chronic ulcer of right calf limited to breakdown of skin
L97.212	Non-pressure chronic ulcer of right calf with fat layer exposed
L97.221	Non-pressure chronic ulcer of left calf limited to breakdown of skin
L97.222	Non-pressure chronic ulcer of left calf with fat layer exposed

Advanced Therapy
Documentation Considerations

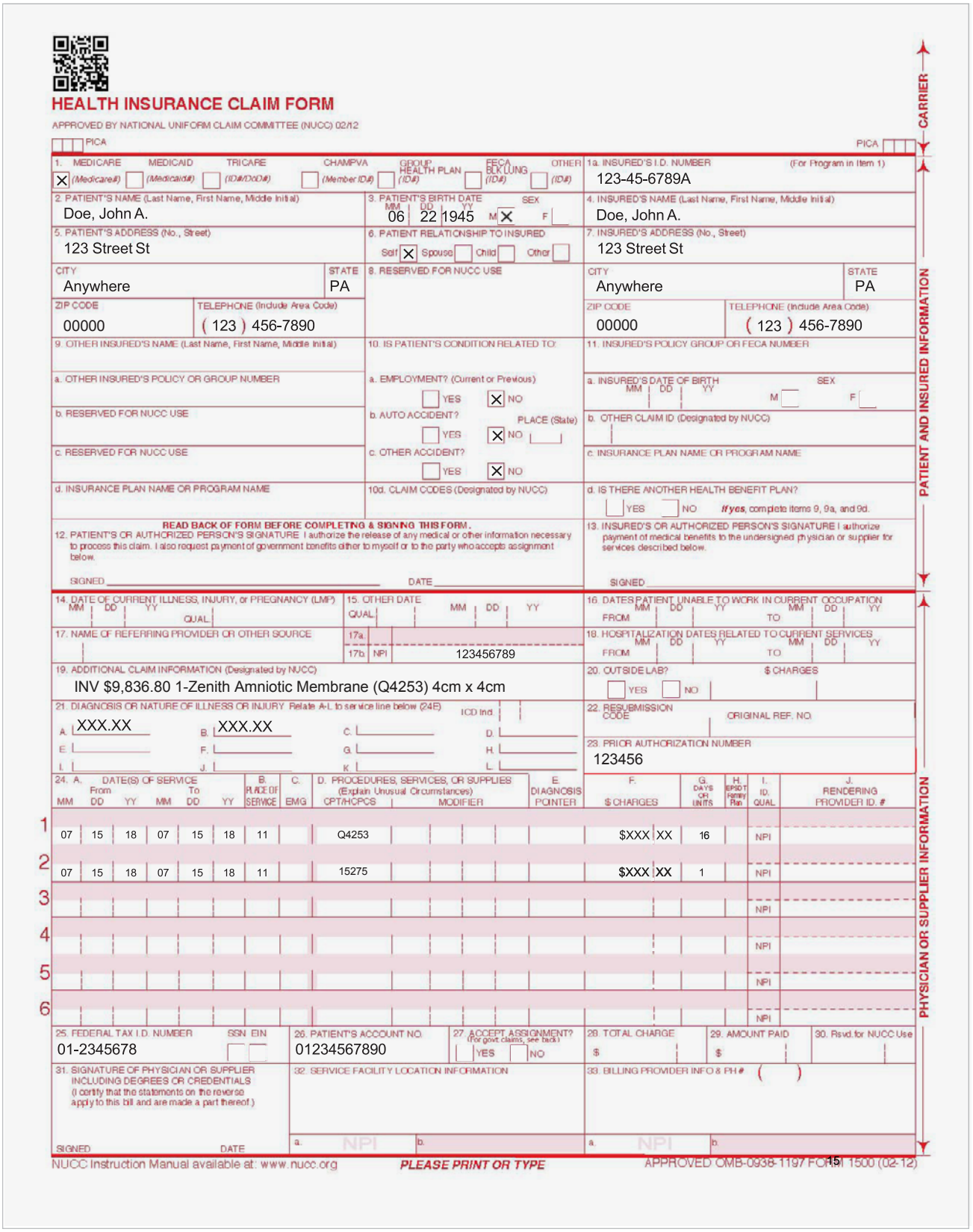
Prior to requesting insurance verification or prior authorization from a payer or submitting a claim for an advanced wound healing product, the provider should verify applicable coverage and documentation requirements with the payor.

Common criteria and documentation elements required of payors include the following in the patient's medical record:

- Determine the Medical Necessity
- Duration of ulcer
- Location of ulcer
- Whether the ulcer has failed to respond to conservative measures
- Baseline measurements of the ulcer
- If applicable, describe the treatment of the underlying disease process contributing to the ulcer
- Indicate the appropriate patient diagnosis codes
- Status of the wound, including (as applicable) presence or absence of cellulitis, infection, tunnels, tracts, eschar, or necrotic material
- Extent of the ulcer (e.g., dermis, involvement of tendon, muscle, capsule, or bone, etc.)
- For diabetic foot ulcers, whether the patient exhibits neuropathy
- Evaluation of venous sufficiency / insufficiency ulcers
- Whether the patient is competent, and/or has the support services necessary to participate in follow-up-care

Claim Forms

Sample CMS 1500 paper Claim Form



HEALTH INSURANCE CLAIM FORM

APPROVED BY NATIONAL UNIFORM CLAIM COMMITTEE (NUCC) 02/12

PICA

1. MEDICARE [X] (Medicare#) | MEDICAID [ ] (Medicaid#) | TRICARE [ ] (ID#/DoD#) | CHAMPVA [ ] (Member ID#) | GROUP HEALTH PLAN [ ] (ID#) | FECA BLK LUNG [ ] (ID#) | OTHER [ ] (ID#)

1a. INSURED'S I.D. NUMBER (For Program in Item 1): 123-45-6789A

2. PATIENT'S NAME (Last Name, First Name, Middle Initial): Doe, John A.

3. PATIENT'S BIRTH DATE: 06 22 1945 SEX: M [X] F [ ]

4. INSURED'S NAME (Last Name, First Name, Middle Initial): Doe, John A.

5. PATIENT'S ADDRESS (No., Street): 123 Street St

6. PATIENT RELATIONSHIP TO INSURED: Self [X] Spouse [ ] Child [ ] Other [ ]

7. INSURED'S ADDRESS (No., Street): 123 Street St

CITY: Anywhere | STATE: PA

8. RESERVED FOR NUCC USE

CITY: Anywhere | STATE: PA

ZIP CODE: 00000 | TELEPHONE (Include Area Code): (123) 456-7890

ZIP CODE: 00000 | TELEPHONE (Include Area Code): (123) 456-7890

9. OTHER INSURED'S NAME (Last Name, First Name, Middle Initial)

10. IS PATIENT'S CONDITION RELATED TO:

11. INSURED'S POLICY GROUP OR FECA NUMBER

a. OTHER INSURED'S POLICY OR GROUP NUMBER

a. EMPLOYMENT? (Current or Previous) YES [ ] NO [X]

a. INSURED'S DATE OF BIRTH MM DD YY SEX M [ ] F [ ]

b. RESERVED FOR NUCC USE

b. AUTO ACCIDENT? YES [ ] NO [X] PLACE (State)

b. OTHER CLAIM ID (Designated by NUCC)

c. RESERVED FOR NUCC USE

c. OTHER ACCIDENT? YES [ ] NO [X]

c. INSURANCE PLAN NAME OR PROGRAM NAME

d. INSURANCE PLAN NAME OR PROGRAM NAME

10d. CLAIM CODES (Designated by NUCC)

d. IS THERE ANOTHER HEALTH BENEFIT PLAN? YES [ ] NO [ ] If yes, complete items 9, 9a, and 9d.

READ BACK OF FORM BEFORE COMPLETING & SIGNING THIS FORM.

12. PATIENT'S OR AUTHORIZED PERSON'S SIGNATURE I authorize the release of any medical or other information necessary to process this claim. I also request payment of government benefits either to myself or to the party who accepts assignment below.

SIGNED _____ DATE _____

13. INSURED'S OR AUTHORIZED PERSON'S SIGNATURE I authorize payment of medical benefits to the undersigned physician or supplier for services described below.

SIGNED _____

14. DATE OF CURRENT ILLNESS, INJURY, or PREGNANCY (LMP) MM DD YY QUAL.

15. OTHER DATE QUAL. MM DD YY

16. DATES PATIENT UNABLE TO WORK IN CURRENT OCCUPATION MM DD YY FROM TO MM DD YY

17. NAME OF REFERRING PROVIDER OR OTHER SOURCE

17a.

17b. NPI 123456789

18. HOSPITALIZATION DATES RELATED TO CURRENT SERVICES MM DD YY FROM TO MM DD YY

19. ADDITIONAL CLAIM INFORMATION (Designated by NUCC)
INV $9,836.80 1-Zenith Amniotic Membrane (Q4253) 4cm x 4cm

20. OUTSIDE LAB? YES [ ] NO [ ] $ CHARGES

21. DIAGNOSIS OR NATURE OF ILLNESS OR INJURY Relate A-L to service line below (24E) ICD Ind.
A. XXX.XX B. XXX.XX C. D. E. F. G. H. I. J. K. L.

22. RESUBMISSION CODE ORIGINAL REF. NO.

23. PRIOR AUTHORIZATION NUMBER: 123456

24. A. DATE(S) OF SERVICE From MM	DD	YY	To MM	DD	YY	B. PLACE OF SERVICE	C. EMG	D. PROCEDURES, SERVICES, OR SUPPLIES (Explain Unusual Circumstances) CPT/HCPCS	MODIFIER	E. DIAGNOSIS POINTER	F. $ CHARGES	G. DAYS OR UNITS	H. EPSDT Family Plan	I. ID. QUAL	J. RENDERING PROVIDER ID. #
1	07	15	18	07	15	18	11		Q4253			$XXX XX	16		NPI	
2	07	15	18	07	15	18	11		15275			$XXX XX	1		NPI	
3															NPI	
4															NPI	
5															NPI	
6															NPI	

25. FEDERAL TAX I.D. NUMBER SSN EIN: 01-2345678

26. PATIENT'S ACCOUNT NO.: 01234567890

27. ACCEPT ASSIGNMENT? (For govt. claims, see back) YES [ ] NO [ ]

28. TOTAL CHARGE $

29. AMOUNT PAID $

30. Rsvd. for NUCC Use

31. SIGNATURE OF PHYSICIAN OR SUPPLIER INCLUDING DEGREES OR CREDENTIALS (I certify that the statements on the reverse apply to this bill and are made a part thereof.)
SIGNED DATE

32. SERVICE FACILITY LOCATION INFORMATION
a. NPI b.

33. BILLING PROVIDER INFO & PH # ( )
a. NPI b.

CARRIER

PATIENT AND INSURED INFORMATION

PHYSICIAN OR SUPPLIER INFORMATION

NUCC Instruction Manual available at: www.nucc.org

PLEASE PRINT OR TYPE

APPROVED OMB-0938-1197 FORM 1500 (02-12)

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Claim Forms

Insurance Verification Request Form

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Patient Insurance Verification and Prior Authorization Request Form

❑ New patient ❑ Re-verification ❑ Additional applications ❑ New insurance

Sales representative name _____

Patient and Insurance Information

Patient name	Date of birth		
Address	City	State	Zip

Is the patient currently residing in a skilled nursing facility? ❑ Yes ❑ No If yes, is the patient covered under a Part A stay? ❑ Yes ❑ No

If patient is currently under a surgical global period, please indicate date and procedure completed

Procedure (CPT) code(s)		Date of procedure
Primary insurance	Policy #	Payer phone
Secondary insurance	Policy #	Payer phone
Tertiary insurance	Policy #	Payer phone
Workers comp claim #	Adjuster name	Adjuster phone

Physician and Facility Information

Physician name	Physician specialty		
NPI #	Medicare (PTAN) provider #		
Tax ID	Medicaid provider #		
Office contact	Phone	Fax	

Treating facility place of service (POS)
❑ Hospital-based outpatient wound department (HOPD – POS 22) ❑ Ambulatory surgery center (ASC – POS 24)
❑ Physician office (POS 11)
❑ Other (please specify, e.g. critical access hospital or POS 19 off-campus) _____

Facility name			
Facility address	City	State	Zip
NPI #	Tax ID		
Medicare contractor (MAC) and Provider ID (PTAN) for claims processing			

Product and Treatment Information

Product: ❑ (Q4253) Zenith ❑ (Q4262) Impax ❑ (Q4268) SurGraft FT

Application codes: 15271 – 15274 for wounds on the trunks, arms, and/or legs
15275 – 15278 for wounds on the face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits

Anticipated treatment start date	Number of applications	Frequency
Total surface area of all wounds		

Diabetic foot ulcer	Venous leg ulcer	Pressure ulcer or chronic wound	Other
E code	I code	L code	
L code	L code		

I certify I have obtained a valid authorization under applicable law from the patient listed on this form (a) permitting me to release the patient's protected health information to Legacy Medical and its contractors to research insurance coverage regarding Legacy Medical products, and to provide me with reimbursement assistance services regarding such products; and (b) authorizing the payer to disclose PHI to Legacy Medical and its contractors for the purposes of determining benefit coverage.

Provider signature _____ Date _____

Please send form along with a copy of the front and back of patient's insurance card to sunderwood@prodatamgmt.com or fax to (866) 205-0732.

If further assistance is needed, please contact IVR Support Team at (919) 249-7293 for additional support.

Disclaimer: Legacy Medical offers insurance verification as an information service only. Information gathered during the requested research will be provided by the insurer or third-party payer. Results of this research are not a guarantee of coverage or reimbursement in the future. Legacy Medical disclaim liability for payment of any claims, benefits, or costs.

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Coverage Summary

Skin Substitute Graft Procedures

The coverage landscape for Skin Substitute Graft Procedures varies by insurance carrier. Please review policies for all payors on a regular basis for updates and changes. Coverage defines what medical technologies, services, and procedures a health plan will reimburse, and generally varies by payor. Private health plans, as well as Medicare, may vary in their consideration of coverage for a particular technology or procedure. Further, the patient's individual benefit plan will delineate what items and services may be covered by the health plan. It is the provider's and patient's responsibility to verify coverage based upon the patient's health plan, individual plan benefit, and applicable medical necessity criteria.

Case by case pre-authorization approval should be considered following specific payor guidelines for the pre-authorization and appeal process. Please check and confirm the insurer's specific medical policies and pre-authorization guidelines to help facilitate the attainment of coverage. Pre-authorization signifies that the health plan has given a preliminary approval of treatment for that individual patient before the procedure has occurred. Final approval and reimbursement is only provided after the pre-authorized service is delivered, required documentation completed, and submission of the claim for adjudication by the health plan.

Glossary of Reimbursement Terms

Medicare Area Contractors (MAC): The Centers for Medicare and Medicaid Services (CMS) contracts with regional Medicare Area Contractors (MACs) to administer the Medicare program. Each MAC establishes its own set of guidelines for the coverage of services. Coverage guidelines are published by each MAC as a Local Coverage Determination (LCD).

Coinsurance/Deductibles: Medicare reimburses 80 percent of the allowable amount for most items and services covered under Medicare Part B, including those related to wound care provided in the outpatient setting. The patient, or secondary/supplemental plan, is responsible for the remaining 20 percent coinsurance amount. The appropriate annual deductibles also apply.

APC: Ambulatory Payment Classification

Fee for Service: Medicare reimburses physician offices for Zenith Amniotic MembraneTM as a fee-for-service for separate services provided. Products are reimbursed when purchased by the provider and incident to the physician service. CMS lists for Zenith Amniotic MembraneTM reimbursement rates on their quarterly ASP Pricing File. CMS requires qualified healthcare providers to bill using the appropriate HCPCS and CPT codes and to accurately report the units of service.

Physician Office (Place of Service – 11): The physician office is defined as a location other than a hospital, skilled nursing facility (SNF), military treatment facility, community health center, state, or local public health or intermediate care facility (ICF), where the health professional routinely provides health examinations, diagnosis and treatment of illness or injury on an ambulatory basis.

Ulcer Size: Determining the wound location and surface area is important in order to select the appropriate CPT and ICD-10 codes. Wound size, as measured according to acceptable practice standards, should be documented in the medical record weekly, including the Length (L), Width (W) and Depth (D) in cm. Initial coverage is typically based on documentation that the wound is not improving, or reducing in size over time, and has become a chronic ulcer.

Supportive Literature

The following literature links may provide additional information about the use of Zenith Amniotic Membrane™ acellular amnion fluid or dehydrated amniotic membrane allograft to support medical necessity.

- Litwiniuk, Malgorzata and Tomasz Grzela. "Amniotic membrane: new concepts for an old dressing". *Wound Repair and Regeneration* 22.4 (2014): 451-456. Access at: https://onlinelibrary.wiley.com/doi/full/10.1111/wrr.12188
- Haugh AM, Witt JG, Hauch A, et al. Amnio Membrane in Diabetic Foot Wounds: A Meta-analysis. *Plastic and Reconstructive Surgery Global Open.* 2017; 5(4):e1302. Access at: http://dx.doi.org/10.1097/GOX.0000000000001302
- Zelen CM, "An Evaluation of Dehydrated Human Amniotic Membrane Allografts in Patients with DFUs" *J Wound Care* 2013 Jul: 22(7):347-8, 350-1.
- Guo X, Mu D, Gao F. "Efficacy and Safety of acellular dermal matrix in diabetic foot ulcer treatment: A systematic review and meta-analysis. *Int J Surg.* 2017 Apr; 40:1-7 Access at: https://www.ncbi.nlm.nih.gov/pubmed/28232031
- Cazzell S, Vayser D. A Randomized Clinical Trial of a Human Acellular Dermal Matrix Demonstrated Superior Healing Rates for Chronic Diabetic Foot Ulcers Over Conventional Care Access at: Access at: https://www.ncbi.nlm.nih.gov/pubmed/28544150
- Cornwell KG, Landsman A. Extracellular Matrix Biomaterials for Soft Tissue Repair. *Clin Podiatric Med Surg.* 2009; Oct; 26(4): 507-23. Access at: https://www.ncbi.nlm.nih.gov/pubmed/19778685

Resources for Zenith Amniotic Membrane™ Technology Support

The following resources can provide support when preparing a pre-authorization for the Zenith Amniotic Membrane™ skin substitute graft procedure when performed in the office, outpatient or surgery center setting of care.

These resources have been referenced in this guide and can be provided when required.

- Zenith Amniotic Membrane™ Product Brochures
- Instructions for Use (IFU)

For ICD-10-CM/PCS code mappings access the following links:

- http://www.cms.gov/Medicare/Coding/ICD10/2018-ICD-10-PCS-and-GEMs.html
- http://www.cms.gov/Medicare/Coding/ICD10/2018-ICD-10-CM-and-GEMs.html

The following links can also provide information to assist providers when procedures and technologies are considered for reimbursement.

- AMA CPT Code Search Tool
- Medicare Physician Fee Schedule Look-up Tool
- American Association of Tissue Banks (AATB)
- National Association of Insurance Commissioners (NAIC) Homepage
- OMHA ALJ Appeal Status Information System (AASIS)

Documentation Support

The information in the following pages must be requested from the clinician directly to the reimbursement department.

Documentation Support for Prior Authorization

Documentation of a patient's history, conservative therapies and reason for any service or procedure is the key to a positive reimbursement scenario. When a skin substitute graft procedure is indicated by the physician, the patient's medical record should clearly state the reason for the procedure as well as the outcomes and recommended therapies to follow. This documentation will support claim review and pre-authorization alike. Follow-up or staged procedures will depend on the initial documentation to support medical necessity. The following general documentation guidelines should be followed for all payors.

Clinical notes should contain the following details:

- Reason for the procedure based on physical exam
- All conservative therapies previously used in the treatment of the current disease
- Specific reason why this treatment is indicated for this patient
- Anticipated outcomes
- Recommended therapies or treatments

Operational and office visit notes might include the following:

- History of patient encounters including conservative therapies
- Current diagnosis or history of disease state
- Details of findings on exam
- Reason for procedure relevant to condition
- Usual details of procedure
- Explanation of technology specific to Zenith Amniotic Membrane™
- Findings and any anticipated further treatments

A letter of medical necessity (LMN) may be required for pre-authorization of a skin substitute graft procedure or for supporting documentation following a request for a claim review. Details of the LMN should include the items on the checklist above. An example LMN is provided in the following section of this guide.

Pre-Authorization

Pre-Authorization Overview

In order to facilitate coverage access for a proposed procedure, the physician may request a pre-authorization from the patient's private insurance carrier. Some health plans require pre- authorization for all surgical procedures. Requesting pre-authorization may only involve a simple contact by the physician's office to verify benefits and acquire an approval number to submit with the claim. Alternatively, pre-authorization may require that the physician provide more substantive information about the case. To prepare a pre-authorization request that requires additional information beyond basic coding, the physician's staff must provide technical information about the procedure and the unique technology involved. The treating physician must also establish the medical necessity for the procedure, as it applies to the specific patient.

Typically, the pre-authorization process and/or appeal process may require submitting some or all of the following documentation:

- Patient clinical notes, including documentation of prior conservative care
- Supporting technical information in the form of the FDA registration letter, peer- reviewed clinical literature, clinical trial information and other available technical resources
- Description of the technology and its use in this patient's case
- Description of medical necessity of the procedure for the specific patient

Pre-Authorization

Zenith Amniotic Membrane Pre-Authorization/LMN – Example Letter

PRE-AUTHORIZATION/LETTER OF MEDICAL NECESSITY

Providers, please note: *Coverage requirements will typically vary by payor. Therefore, physicians may seek pre-authorization for the procedure, during which time health plans will determine whether the procedure is covered as described in the pre-authorization submission. Providers should select the procedure, diagnosis, and technology coding that best represents each patient's medical condition and treatment and should reflect the services and products that are medically necessary for the treatment of that patient. Providers must ensure that all statements made to insurance carriers are true and correct.*

[DATE]
[NAME OF INSURANCE COMPANY]
[ATTN:]
[FAX #:]

RE: [PATIENT NAME]
[INSURANCE IDENTIFICATION NUMBER]
[REFERENCE #:]
[PRIMARY CPT CODE:]
[PRIMARY DX:]

Dear Utilization Review Manager:
On behalf of my patient, [PATIENT NAME], this letter serves as a pre-authorization request and provides clinical information on this patient's condition. It also serves as a formal request for coverage by [INSURANCE COMPANY] for the medically necessary health care services captioned above. This letter and its supporting documents will provide you with a better depiction of this patient's clinical history and this patient's need for the [ZENITH AMNIOTIC MEMBRANE™ SKIN SUBSTITUTE GRAFT PROCEDURE]. It is my sincere hope that this additional information will inform your decision to approve this surgery.
Description of Procedure: [PHYSICIAN INSERTS DETAILED PROCEDURE DESCRIPTION INCLUDING THE USE OF THE ZENITH AMNIOTIC MEMBRANE™ SKIN SUBSTITUTE GRAFT].

Skin Substitute Description: Zenith Amniotic Membrane™ is a dehydrated amniotic membrane allograft intended to be used for homologous use to cover a recipient's tissue. It provides an adhesion barrier for adjacent soft tissues and promotes wound healing. Zenith Amniotic Membrane™ is ready to use and is available in various sizes for improved handling, delivery and optimal coverage.
Key Benefits of Zenith Amniotic Membrane™ Skin Graft Substitute:

- Amniotic membrane expresses immune-privileged antigens
- An immune tolerant graft with negligible risk of foreign body reaction
- Limits the expression of inflammatory cytokines
- Reduces fibrosis, scarring and post-operative pain.

Patient's Clinical Need for the [ZENITH AMNIOTIC MEMBRANE™] ***Skin Substitute Graft Procedure:*** [PATIENT NAME] is a [AGE] [GENDER] who presented to me with [DESCRIBE SYMPTOMS WITH SPECIFICITY]. Prior treatments have included [DESCRIBE CONSERVATIVE CARE, USE OF MEDICATIONS, PRIOR TREATMENTS, and PHYSICAL AIDS].

In a discussion with [INSERT MR/MS] following an exam, a decision was made to move forward with a skin substitute graft procedure. The amniotic and placental properties of [ZENITH AMNIOTIC MEMBRANE™ SKIN SUBSTITUTE GRAFT] allows for easy application, making it a flexible, dependable option for wound and soft tissue healing for my patient.

Should you have further questions or concerns, please do not hesitate to call me at [INSERT PHYSICIAN TELEPHONE NUMBER]. Thank you for your immediate attention and anticipated authorization of these services for your insured.

Sincerely,

[PHYSICIAN NAME], [DEGREE]

Plan Denial Appeal Process

Plan Denial Appeal Process Overview

When a third-party health plan denies a procedure in accordance with their medical policy guidelines, there is a process available to appeal that decision. Insurance carriers provide this check and balance to allow for reconsideration of the decision per their plan provisions and applicable state regulations. The process will vary depending on the plan and regulatory requirements; however, there are basic steps that can assist the provider in appealing the initial denial.

To present an effective appeal, follow these steps:

1. Carefully review the denial reason and understand the specific health plan's policy.
2. Write an appeal letter clearly addressing the specific denial reasons.
3. Provide supporting information including product details and FDA registration; and
4. Submit the appeal on time.

The following additional considerations may be helpful:

1. If the health plan is self-funded (employer based), patients can contact their Human Resources (HR) department to assist in the patient's appeal of the decision. HR departments may have contacts within the health plan that can provide helpful support.
2. The patient can contact the health plan directly and is the policyholder with an influence on the decision.
3. There are multiple steps in the appeal process and providers and patients may exercise these rights according to their third-party payor and state guidelines.

Writing the Appeal Letter

When appealing a denial, the first step is often composing a letter to the health plan that initially reviewed the case. This letter is submitted by the provider on behalf of the patient, with the patient's approval, and should outline the reasons the denial should be overturned.

Detailed information regarding the denial reason should be prepared utilizing the case specific information in the denial, as well as the more general technology specific information and supporting clinical literature.

First, collect all the information required to support the appeal:

- Denial letter
- Health plan contracts and provider agreements
- Applicable medical policy guidelines from the health plan (website access is often a good resource for general policy)
- Literature supporting the technology
- FDA registration letter
- Safety and effectiveness documentation
- Peer-reviewed literature references (when available)

In drafting an appeal letter, consider the following:

- Did the reviewer overlook a case specific detail?
- Does the health plan clearly understand the procedure?
- Was the information provided about the case correctly submitted?
- Review the plan's official policy online for more detailed understanding of the denial reason

Plan Denial Appeal Process

Zenith Amniotic Membrane PA Denial Appeal – Example Letter

ZENITH AMNIOTIC MEMBRANE PRE-AUTHORIZATION APPEAL LETTER

Providers, please note: *Despite the filing of a pre-authorization request, certain commercial health plans may still elect not to cover or grant pre-authorization for this procedure without further information and clinical evidence supporting its use. Should pre-authorization be denied, the physician requesting coverage should immediately file a written appeal with the health plan and request reconsideration of the coverage decision. When requesting a pre-authorization appeal it is important to remember that payors may require all elements of a procedure to be pre-authorized per their payor guidelines. To assist you, the following example is offered as a starting point for your pre-authorization denial appeal and reconsideration request.*

[DATE]
[NAME OF INSURANCE COMPANY] [ATTN:]
[FAX #:]

RE: [PATIENT NAME]
[INSURANCE IDENTIFICATION NUMBER] [REFERENCE #:]
[PRIMARY CPT CODE]
[PRIMARY DX CODE]

Dear Utilization Review Manager:
Please accept this letter on behalf of [PATIENT NAME], as an appeal to [INSURANCE COMPANY]'s decision to deny coverage for the recommended [PROCEDURE]. It is my understanding, per [INSURANCE COMPANY]'s denial letter dated [INSERT DENIAL LETTER DATE], that this procedure has been denied because [REASON FOR DENIAL].

I respectfully request that [INSURANCE COMPANY] reconsider its denial and provide authorization for this treatment option. I believe this denial was made in error. This letter and its supporting documents will provide you with a better depiction of this patient's clinical history and this patient's need for the [ZENITH AMNIOTIC MEMBRANE™ SKIN SUBSTITUTE GRAFT PROCEDURE]

Description of Procedure: [PHYSICIAN INSERTS DETAILED PROCEDURE DESCRIPTION INCLUDING THE USE OF THE [ZENITH AMNIOTIC MEMBRANE™ SKIN SUBSTITUTE GRAFT PROCEDURE]

Skin Substitute Description: Zenith Amniotic Membrane™ is a dehydrated amniotic membrane allograft intended to be used for homologous use to cover a recipient's tissue. It provides an adhesion barrier for adjacent soft tissues and promotes wound healing.

Zenith Amniotic Membrane™ is ready to use and is available in various sizes for improved handling, delivery and optimal coverage. The strength of the allograft allows for suturing in place and no bulk at the surgical site.
Key Benefits of Zenith Amniotic Membrane™ Skin Graft Substitute:

- Amniotic membrane expresses immune-privileged antigens
- An immune tolerant graft with negligible risk of foreign body reaction
- Limits the expression of inflammatory cytokines
- Contain large amounts of hyaluronic acid that entrap inflammatory cells.

[ZENITH AMNIOTIC MEMBRANE™] is regulated by the U.S. Food and Drug Administration (FDA) as a human skin tissue under its Human Cells, Tissues, and Tissue-Based Products (HCT/P) guidelines, subject to Section 361 of the Public Health Service Act and 21 CFR 1270 and 1271.

(continued on next page)

Plan Denial Appeal Process

Zenith Amniotic Membrane PA Denial Appeal – Example Letter (continued)

[ZENITH AMNIOTIC MEMBRANE™]is an appropriate clinical option in the treatment of chronic, non-infected, partial or full thickness diabetic lower extremity ulcers; chronic, non-infected, full thickness diabetic lower extremity skin ulcers due to venous insufficiency which have not adequately responded following conventional ulcer therapy; second- or third-degree burns.

Please consider the following references in support of [ZENITH AMNIOTIC MEMBRANE™] procedures:

- Litwiniuk, Malgorzata and Tomasz Grzela. "Amniotic membrane: new concepts for an old dressing". *Wound Repair and Regeneration* 22.4 (2014): 451-456. Access at: https://onlinelibrary.wiley.com/doi/full/10.1111/wrr.12188
- Haugh AM, Witt JG, Hauch A, et al. Amnio Membrane in Diabetic Foot Wounds: A Meta-analysis. *Plastic and Reconstructive Surgery Global Open.* 2017; 5(4):e1302. Access at: http://dx.doi.org/10.1097/GOX.0000000000001302
- Zelen CM, "An Evaluation of Dehydrated Human Amniotic Membrane Allografts in Patients with DFUs" J Wound Care 2013 Jul: 22(7):347-8, 350-1.

Patient's Clinical Need for the [ZENITH AMNIOTIC MEMBRANE™]
Skin Substitute Graft Procedure: [PATIENT NAME] is a [AGE] [GENDER] who presented to me with [DESCRIBE SYMPTOMS WITH SPECIFICITY]. Prior treatments have included [DESCRIBE CONSERVATIVE CARE, USE OF MEDICATIONS, PRIOR TREATMENTS, and PHYSICAL AIDS].

To assist in your reconsideration of this patient's clinical need for the intended procedure, a copy of the relevant clinical notes that support use of the [ZENITH AMNIOTIC MEMBRANE™ SKIN SUBSTITUTE GRAFT] is enclosed to support you with your decision to overturn your initial denial of coverage for these services. It is my sincere hope that [INSURANCE COMPANY] will respond with a positive decision so that [PATIENT NAME] can benefit from the results of this procedure. Should you have further questions or concerns, please do not hesitate to call me at [INSERT PHYSICIAN TELEPHONE NUMBER].

Thank you for your immediate attention and reconsideration.

Sincerely,

[PHYSICIAN NAME],
[DEGREE] [PRACTICE

ZENITH
AMNIOTIC MEMBRANE

References

1. CMS Manual for that detail Section 20.1.3: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c17.pdf
2. 312> AMA CAT© Professional
3. https://www.cms.gov/medicaremedicare-fee-service-paymentphysicianfeeschedpfs-federal-regulation-notices/ems-1734-p

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