MEDICAL POLICY

Excellus

SUBJECT: BIOENGINEERED TISSUE PRODUCTS FOR WOUND TREATMENT AND SURGICAL INTERVENTIONS	**EFFECTIVE DATE: 01/17/02** **REVISED DATE: 01/16/03, 03/18/04, 01/20/05, 03/16/06, 12/21/06, 01/17/08, 02/19/09, 05/27/10, 08/18/11, 08/16/12, 07/18/13**
POLICY NUMBER: 7.01.35	
CATEGORY: Technology Assessment	**PAGE: 1 OF: 15**

- ***If the member's subscriber contract excludes coverage for a specific service it is not covered under that contract. In such cases, medical policy criteria are not applied.***
- ***Medical policies apply to commercial and Medicaid products only when a contract benefit for the specific service exists.***
- ***Medical policies only apply to Medicare products when a contract benefit exists and where there are no National or Local Medicare coverage decisions for the specific service.***

POLICY STATEMENT:

I. Based upon our criteria and review of the peer-reviewed literature, bioengineered tissue products have been proven to be medically effective and are **medically appropriate** for the treatment of *venous ulcers of the lower extremities* and for *diabetic foot ulcers* that have not responded to a comprehensive program of wound care. Only products that have received FDA approval for this purpose are considered medically appropriate.

A. For treatment of *venous ulcers*, Apligraf® or Oasis™ Wound Matrix may be used when all of the following criteria are met:
1. The patient has adequate arterial blood supply as evidenced by ankle-brachial index (ABI) of 0.65 or greater in the limb being treated;
2. The patient is competent and/or has support system required to participate in follow-up care associated with treatment with a bioengineered tissue product;
3. Ulcers are partial or full thickness and of greater than three (3) months duration;
4. Ulcers have failed to respond to conservative measures of greater than two (2) months duration that have at a minimum included regular dressing changes, debridement of necrotic tissue, and standard therapeutic compression. ("Failure to respond" is defined as increase in size or depth or no change in size or depth with no sign or indication that improvement is likely, such as granulation, epithelialization, or progress toward closing);
5. Patient has adequate treatment of the underlying disease process(es) contributing to the ulcer; and
6. Ulcers are free of infection, redness, drainage, underlying osteomyelitis, surrounding cellulitis, tunnels and tracts, eschar or any necrotic material that would interfere with adherence of a bioengineered tissue product and wound healing.

B. For treatment of *diabetic foot ulcers*, Apligraf® or Dermagraft® may be used when all of the following criteria are met:
1. The patient has adequate arterial blood supply as evidenced by ankle-brachial index (ABI) of 0.65 or greater in the limb being treated;
2. The patient is competent and/or has support system required to participate in follow-up care associated with treatment with a bioengineered tissue product;
3. Ulcers are full thickness and of greater than three (3) weeks duration which extend through the dermis but without tendon, muscle, capsule or bone exposure;
4. Patient has adequate treatment of underlying disease process(es) contributing to the ulcer;
5. Ulcers are located on foot or toes and are free of infection, redness, drainage, underlying osteomyelitis, surrounding cellulitis, tunnels and tracts, eschar or any necrotic material that would interfere with adherence of a bioengineered tissue product and wound healing; and
6. Patient's current HbA1C does not exceed 12%.

II. Based upon our criteria and review of the peer-reviewed literature, the use of AlloDerm® is considered **medically appropriate** for the following indications:
A. Breast reconstruction surgery following surgical mastectomy, and
B. Nasal repairs (e.g., septal repair, septal perforation repair, reconstructive septorhinoplasty), and

C. Non-primary hernia repair when chronic infection contraindicates the use of mesh or other conventional repair; and
D. Parotidectomy.

III. Based upon our criteria and review of the peer-reviewed literature, Biobrane®, Epicel®, Integra® Dermal Regeneration Template and TranCyte™ have been proven to be medically effective and are therefore **medically appropriate** for the treatment of *burns*.

A. For the treatment of *severe* full-thickness burns (e.g. greater than or equal to 20% total body surface area and/or excision to the fascia to remove all nonviable tissue) or deep partial-thickness thermal injury using Integra® Dermal Regeneration Template, all of the following criteria must be met:
1. The patient is competent to understand the need for immobilization and the need for a second surgical procedure for application of an ultra-thin epidermal graft, regular follow-ups, and rehabilitation;
2. Insufficient autograft is available at the time of burn excision; and
3. The burn site is free of residual eschar.

The use of Integra® Dermal Regeneration Template is contraindicated for patients with the following:
A. Known hypersensitivity to bovine collagen, silicone, or chondroitin materials;
B. Pregnancy;
C. Clinically diagnosed infected wounds.

B. For the treatment of thermal injuries, superficial scald burn or flame injury of the hand using Biobrane®, all of the following criteria must be met:
1. The patient is competent and/or has the support system required to participate in follow-up care associated with treatment with a bioengineered tissue product;
2. The burn is superficial, partial-thickness with limited involvement of the dermis (less than or equal to 25% total body surface area);
3. The burn is clean, non-infected, and free of nonviable tissue and coagulation eschar; and
4. The patient is competent to understand the need for immobilization.

IV. Based upon our criteria and the lack of peer-reviewed literature, all other bioengineered tissue products have not been proven medically effective and are considered **investigational** for all other applications. These products include, but are not limited to, the following:

A. AlloPatch HD™
B. AlloMax™ (previously NeoForm™)
C. AlloSkin™
D. AlloSkin™ RT
E. ArthroFlex™ (FlexGraft)
F. Avaulta Plus™
G. BioDfence/BioDfactor
H. CellerateRX®
I. Conexa™
J. CorMatrix®
K. CRXa™
L. Cymetra®
M. DermaMatrix Acellular Dermis
N. DermaSpan™
O. Durepair Regeneration Matrix®
P. Endoform Dermal Template™
Q. ENDURAgen™
R. EpiFix®
S. E-Z Derm™
T. FlexHD® Acellular Hydrated Dermis
U. GammaGraft
V. Grafix® CORE
W. Grafix® PRIME
X. GraftJacket® Regenerative Tissue Matrix
Y. GraftJacket® Xpress, injectable
Z. hMatrix®
AA. Hyalomatrix® PA
BB. Integra™ Flowable Wound Matrix
CC. Integra™ Bilayer Wound Matrix
DD. InteguPly™
EE. MatriDerm®
FF. MatriStem® Micromatrix
GG. MatriStem® Wound Matrix
HH. MatriStem® Burn Matrix
II. Matrix HD™
JJ. MediHoney®
KK. Mediskin®
LL. MemoDerm™

MM. NeoForm™ (see AlloMax™)
NN. Pelvicol™
OO. Permacol™
PP. Repriza™
QQ. StrataGraft
RR. Strattice™
SS. SurgiMend®
TT. Talymed®
UU. TenoGlide™
VV. TheraSkin®
WW. TranZgraft
XX. Unite™ Biomatrix
YY. Veritas® Collagen Matrix

Refer to the Description section for further information in regard to the products listed in the Policy Statements.

Refer to Corporate Medical Policy #1.01.38 regarding Negative Pressure Wound Therapy (Vacuum Assisted Closure).

Refer to Corporate Medical Policy #2.01.24 regarding Growth Factors for Wound Healing and Other Conditions.

Refer to Corporate Medical Policy #10.01.01 regarding Breast Reconstruction Surgery.

Refer to Corporate Medical Policy #11.01.03 regarding Experimental or Investigational Services.

This policy does not address fibrin sealants (e.g., Tisseel).

POLICY GUIDELINES:

I. Utilization of specific products are medically appropriate only when used in accordance with FDA product approval and when the above policy criteria are met.

II. A single application of a bioengineered tissue product is usually all that is required to affect wound healing in wounds likely to be improved by this treatment. Re-application of a product is appropriate only if there has been measurable response to the first application. Re-application in less than one year after successful treatment is not medically appropriate.

III. Treatment of venous stasis ulcers that extend above the malleoli is beyond the scope of practice of podiatrists.

IV. The Federal Employee Health Benefit Program (FEHBP/FEP) requires that procedures, devices or laboratory tests approved by the U.S. Food and Drug Administration (FDA) may not be considered investigational and thus these procedures, devices or laboratory tests may be assessed only on the basis of their medical necessity.

DESCRIPTION:

Bioengineered tissue products are used for burns, chronic wounds, and rare skin diseases and are proposed for use in many other conditions. They aid in the growth of new skin or serve as a temporary cover until other grafts can be placed. Bioengineered tissue products and their uses/ proposed uses include, but are not limited to:

Biologic tissue product	Class	Use/Proposed Use	FDA approved*	FDA exempt**
*PMA - Wound and burn dressings, class III high risk devices and require clinical data to support claims for use.				
*510(k) - Wound care devices that protect wounds and act as a scaffold for healing.				
**Human tissue - Donated, banked human skin regulated by the American Association of Tissue Banks and FDA guidelines.				
AlloDerm®	Acellular dermal matrix; allogeneic human derived decellularized skin	Burns, wound healing, contaminated abdominal walls, ventral hernia repair, breast reconstruction		Human tissue
AlloMax™ (previously NeoForm™)	Acellular dermal matrix; allogeneic human derived decellularized skin	Breast reconstruction		Human tissue
AlloSkin™	Epidermal and dermal allograft	Partial and full thickness wounds		Human tissue

Biologic tissue product	Class	Use/Proposed Use	FDA approved*	FDA exempt**
Apligraf® (previously Graftskin)	Cellular, bilayered skin substitute; human derived composite cultured skin	Venous and diabetic ulcers	x (PMA)	
ArthroFlex™ (aka FlexGraft)	Decellularized human allograft dermis	Shoulder reconstruction, Achilles tendon repair		Human tissue
Avaulta Plus™	Porcine derived polypropylene composite	Vaginal wall prolapse	X (510k)	
Biobrane®/ Biobrane l®	Synthetic, bilaminate collagen-based composite	Partial thickness burns, temporary covering	x (PMA)	
Collamend	Porcine derived decellularized collagen	Soft tissue weakness, hernia and abdominal wall repair	X (510k)	
Conexa™	Porcine dermis tissue substitute	Soft tissue repair	x (510k)	
Cymetra®	Allogeneic cadaver derived decellularized skin; micronized particulate form of AlloDerm	Soft tissue defects (e.g., laryngoplasty)		Human tissue
Dermagraft®	Interactive wound dressing; human derived composite cultured skin; dermal replacement from neonatal foreskin fibroblasts	Diabetic foot ulcers	x (PMA)	
DermaMatrix	Human skin allograft	Facial soft tissue defects, nasal reconstruction, septal perforation, parotidectomy, cleft palate repair, breast reconstruction, abdominal wall repair		Human tissue
DermaSpan™	Acellular dermal matrix	Repair or replacement of damaged or inadequate integumental tissue		Human tissue
Endoform Dermal Template™	Ovine (sheep) derived extracellular matrix	Partial and full thickness wounds, ulcers, surgical and traumatic wounds, burns	x (510k)	
ENDURAgen™	Porcine dermal acellular collagen matrix	Soft tissue augmentation, reinforcement and repair of the head and face	x (510k)	
Epicel®	Cultured epidermal autograft; combined human and animal dermal cellular material	Full thickness burns over greater than 30% of the body	x (HDE)	
EpiFix	Human amniotic tissue membrane	Partial and full thickness diabetic foot, venous leg, arterial and pressure ulcers		Human tissue
E-Z Derm™	Porcine derived decellularized fetal skin	Partial thickness burns; venous, diabetic and pressure ulcers	x (510k)	
FlexHD®	Acellular dermal matrix	Breast reconstruction, hernia repair		Human tissue

Biologic tissue product	Class	Use/Proposed Use	FDA approved*	FDA exempt**
GammaGraft	Irradiated human skin composite allograft	Temporary graft for burns, chronic wounds and partial and full thickness wounds		Human tissue
Grafix® CORE	Cellular matrix from human placental chorionic membrane	Acute and chronic diabetic foot ulcers, venous stasis ulcers and pressure ulcers		Human tissue
Grafix® PRIME	Cellular matrix from human placental amniotic membrane	Acute and chronic diabetic foot ulcers, venous stasis ulcers and pressure ulcers; burns; adhesion barriers; and Mohs procedures		Human tissue
GraftJacket®	Bilaminate acellular regenerative tissue; allogeneic human derived decellularized skin	Wound repair, tendon and rotator cuff repair		Human tissue
GraftJacket® Xpress	Micronized decellularized soft tissue scaffold	Deep tunneling dermal wounds		Human tissue
Graftskin (see Apligraf)				
Hyalomatrix®	Hyaff 11 (hyaluronic acid) and silicone	Partial and full thickness wounds, ulcers, surgical and traumatic wounds, burns	x (510k)	
hMatrix®	Acellular dermal matrix	Wound covering, abdominal wall repair, breast reconstruction, craniomaxillofacial soft tissue grafting		Human tissue
Integra™	Bovine derived tendon collagen and glycosaminglycan	Partial and full thickness wounds, ulcers, surgical and traumatic wounds, burns	x (510k)	
Integra™ Bilayer Wound® Matrix	Bovine-tendon collagen, glucoseaminoglycan and silicone	Partial and full thickness wounds, ulcers, surgical and traumatic wounds, burns	x (510k)	
Integra™ Dermal Regeneration Matrix®	Bilayered extracellular cross linked bovine collagen and chondroitin sulfate	Partial and full thickness burns	x (PMA)	
Integra™ Flowable Wound®	Granulated cross linked bovine tendon collagen and glycoaminoglycan	Difficult to access and tunneled wounds	x (510k)	
InteguPly™	Acellular dermal matrix	Diabetic ulcers, Charcot foot ulcers, venous ulcers, trauma wounds, pressure ulcers, partial and full thickness wounds, and surgical wounds		Human tissue
Laserskin (see Hyalomatrix)				

Biologic tissue product	Class	Use/Proposed Use	FDA approved*	FDA exempt**
Matristem® Micromatrix	Porcine collagen wound dressing	Partial and full thickness wounds, ulcers, surgical and traumatic wounds, burns	x (510k)	
Matristem® Wound Matrix	Porcine collagen wound dressing	Partial and full thickness wounds, ulcers, surgical and traumatic wounds, burns	x (510k)	
Matristem® Burn Matrix	Porcine collagen wound dressing	Burns	x (510k)	
Mediskin®	Porcine derived decellularized fetal skin, frozen	Partial-thickness skin ulcerations and abrasions, temporary covering for full-thickness skin loss	x (510K)	
Neoform (see Allomax)				
OASIS® Wound Matrix	Collagen matrix from porcine small intestine submucosa, single layer	Full thickness skin injuries, ulcers, surgical wounds	x (510k)	
OASIS® Burn Matrix	Extracellular matrix from porcine small intestine submucosa, bi-layered	Burns	x (510k)	
OASIS® Ultra	Collagen matrix from porcine small intestine submucosa, tri-layered	Full thickness skin injuries, ulcers, surgical wounds	x (510k)	
Orcel™	Composite skin substitute; human derived composite cultured skin; bilayered cellular matrix	Donor sites in burn victims	x (PMA)	
Orthoadapt	Equine derived decellularized collagen	Soft tissue repair, reinforce tendon repairs	x (510k)	
Pelvicol	Porcine derived decellularized collagen	Soft tissue repair	x (510k)	
Pelvisoft	Porcine derived decellularized collagen	Pelvic floor reconstruction	x (510k)	
Permacol™	Acellular porcine dermal collagen and elastin xenograft	Soft tissue repair and reinforcement	x (510k)	
Primatrix	Acellular collagen dermal tissue matrix; fetal bovine derived decellularized skin product	Burns, wounds and pressure, diabetic and venous ulcers	x (510k)	
Restore	Porcine small intestine submucosa	Soft tissue reinforcement	x (510k)	
StrataGraft	NIKS cells, tissue keratinocytes	Burns, skin defects	under develop-ment	
Strattice™	Porcine dermis xenographic tissue	Soft tissue patch	x (510k)	
SurgiMend®	Acellular dermal tissue matrix from fetal bovine dermis	Reinforce soft tissue weakness and surgical repair	x (510k)	

Biologic tissue product	Class	Use/Proposed Use	FDA approved*	FDA exempt**
TheraSkin®	Cryopreserved allogeneic human skin	Wounds and ulcers		Human tissue
Tissuemend	Bovine derived decellularized skin product	Soft tissue and tendon repair reinforcement	x (510k)	
TranCyte ™ (previously DermaGraft)	Biosynthetic skin substitute; human derived composite cultured skin; allogeneic human dermal fibroblasts	Full and partial thickness burns	x (PMA)	
TranZgraft	Acellular dermal matrix	Dental, orthopedic and ENT applications, hernia and ulcer repair		Human tissue
Unite™ Biomatrix	Equine derived decellularized collagen	Chronic wounds and ulcers	x (510k)	
Veritas® Collagen Matrix	Non-cross linked bovine pericardium	Surgical repair of soft tissue deficiencies	x (510k)	

RATIONALE:

AlloDerm® is classified by the FDA as human tissue and is approved for use in burns and full-thickness wounds. There is limited scientific evidence in the form of retrospective case series to support the use of AlloDerm® in rare cases of non-primary hernia repair when chronic infection contraindicates the use of mesh or other conventional repair.

Although the literature investigating the use of AlloDerm® in breast reconstruction surgery consists of small case series that lack long-term data on effectiveness and safety, they all reach favorable conclusions. The use of AlloDerm® obviates many of the current disadvantages to implant breast reconstruction including thinning of muscle layer causing visible rippling and contour irregularities. In the multi-step processing of AlloDerm®, the epidermis and all the dermal cellular components are removed, leaving no reservoir for viral agents. As a result, no immune response is elicited after placement of the allograft.

Literature regarding the use of AlloDerm® in parotidectomy also consists of small case series; however they support that AlloDerm® is beneficial in preventing Frey's syndrome after parotidectomy.

Biobrane® was granted pre-market approval by the FDA as a temporary covering of full-thickness burns until autografting is clinically appropriate.

Integra® Dermal Regeneration Template was granted pre-market approval by the FDA for use in post-excisional treatment of life-threatening full-thickness or deep partial-thickness thermal injuries where sufficient autograft in not available at the time of excision or not desirable due to the physiological condition of the patients, and for the repair of scar contractures when other therapies have failed or when donor sites for repair are not sufficient or desirable due to the physiologic condition of the patient. Evidence for use of Integra for contracture release procedures consists only of a retrospective case series without controls.

Oasis® Wound Matrix, Oasis® Burn Matrix, and Oasis® Ultra Tri-Layer Matrix have FDA 510(k) approval for one-time use in the management of wounds including partial and full thickness wounds, pressure ulcers, venous ulcers, diabetic ulcers, chronic vascular ulcers, tunneled undermined wounds, surgical wounds, trauma wounds, and draining wounds.

PriMatrix™ received FDA 510(k) approval in 2006 for the management of wounds that include: partial and full thickness wounds; pressure, diabetic and venous ulcers; second-degree burns; surgical wounds - donor sites/grafts, post-Moh's surgery, post-laser surgery, podiatric, wound dehiscence; trauma wounds - abrasions, lacerations, and skin tears; tunneled/undermined wounds; draining wounds.

A systematic literature review addressing the current application and limitations of biologic dressings in dermatologic surgery was published in June 2009 (Chern, et al). The review was undertaken to review the current evidence regarding the utility, outcomes, and adverse effects of the available biologic dressings, with a particular focus on use in acute surgical wounds and applicability to dermatologic surgery. The authors concluded that although further work is necessary, biologic dressings remain a promising area of study for use in the healing of acute and chronic wounds, many case reports have described the use of various products in dermatologic disease and cutaneous surgery although further study is necessary before conclusions can be drawn, and overall, further studies, particularly randomized controlled studies, are necessary to evaluate the utility of these biologic dressings, especially in the setting of acute surgical wounds.

In December 2012, AHRQ completed a technology assessment addressing *Skin Substitutes for Treating Chronic Wounds.* The assessment addresses 57 products currently available in the U.S. that are used to manage or treat chronic wounds and are regulated by FDA. Based on FDA regulations skin substitutes can be organized into four groups: human-derived products regulated as HCT/Ps, human- and human/animal-derived products regulated through PMA or HDE, animal-derived products regulated under the 510(k) process, and synthetic products regulated under the 510(k) process. One of the report's goals was to begin to characterize the state of the evidence on skin substitutes as wound care products for chronic wounds. Eighteen RCTs examining only seven of the skin substitute products identified for the report met the inclusion criteria. The author's evaluation of the clinical literature indicates that studies comparing the efficacy of skin substitutes to alternative wound care approaches are limited in number, apply mainly to generally healthy patients, and examine only a small portion of the skin substitute products available in the United States. The results of the available studies cannot be extended to other skin substitute products because of differences in active components in the various products. The studies available were not generalizable to the broader patient populations that are not as healthy as the patients in the studies. Also missing from the evidence base were studies that compared the various types of skin substitute products. Only two of the 18 studies compared two skin substitute products. How a human dermal substitute compares with a human derived skin substitute when treating a diabetic foot ulcer or a vascular leg ulcer is unknown. Such comparisons could be useful to clinicians trying to decide which wound treatment products to use. Additional studies in the area of wound care would be helpful to provide treatment data for many of the other skin substitute products, to allow better comparisons between wound care products, and to provide better information on wound recurrence when using skin substitute products.

CODES: Number Description

Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract.

CODES MAY NOT BE COVERED UNDER ALL CIRCUMSTANCES. PLEASE READ THE POLICY AND GUIDELINES STATEMENTS CAREFULLY.

Codes may not be all inclusive as the AMA and CMS code updates may occur more frequently than policy updates.

Code Key: Experimental/Investigational = (E/I), Not medically necessary/ appropriate = (NMN).

CPT:	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 wound surface area, or part thereof
	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% body area of infants and children, or part thereof
	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 sq cm; first 25 sq cm or less wound surface area

	15276	each additional 25 sq cm wound surface area, or part thereof
	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 and children
	15278	each additional 100 sq cm wound surface area, or part thereof, or each additional 1% body area of infants and children, or part thereof
	15777	Implantation of biologic implant (eg, acellular dermal matrix) for soft tissue reinforcement (eg, breast, trunk)

HCPCS:	Q4100	Skin substitute, not otherwise specified
	Q4101	Apligraf, per square cm
	Q4102	Oasis wound matrix, per square cm
	Q4103	Oasis burn matrix, per square cm
	Q4104 **(E/I)**	Integra bilayer matrix wound dressing (BMWD), per square cm
	Q4105	Integra dermal regeneration template (DRT), per square cm
	Q4106	Dermagraft, per square cm
	Q4107 **(E/I)**	GRAFTJACKET, per square cm
	Q4108	Integra matrix, per square cm
	Q4110	PriMatrix, per square cm
	Q4111 **(E/I)**	GammaGraft, per square cm
	Q4112 **(E/I)**	Cymetra, injectable, 1 cc
	Q4113 **(E/I)**	GRAFTJACKET XPRESS, injectable, 1 cc
	Q4114 **(E/I)**	Integra flowable wound matrix, injectable, 1 cc
	Q4115 **(E/I)**	AlloSkin, per sq cm
	Q4116	AlloDerm, per square cm
	Q4117 **(E/I)**	HYALOMATRIX, per sq cm
	Q4118 **(E/I)**	MatriStem micromatrix, 1 mg
	Q4119 **(E/I)**	MatriStem wound matrix, PSMX, RS, or PSM, per sq cm
	Q4120 **(E/I)**	MatriStem burn matrix, per sq cm
	Q4121 **(E/I)**	TheraSkin, per sq cm
	Q4122 **(E/I)**	DermACELL, per sq cm
	Q4123 **(E/I)**	AlloSkin RT, per sq cm
	Q4124	OASIS ultra tri-layer wound matrix, per sq cm
	Q4125 **(E/I)**	Arthroflex, per sq cm

	Q4126 **(E/I)**	MemoDerm, dermaspan, tranzgraft or integuply, per sq cm
	Q4127 **(E/I)**	Talymed, per sq cm
	Q4128 **(E/I)**	FlexHD, AllopatchHD, or Matrix HD, per sq cm
	Q4129 **(E/I)**	Unite biomatrix, per sq cm
	Q4130 **(E/I)**	Strattice TM, per sq cm
	Q4131 **(E/I)**	Epifix, per sq cm
	Q4132 **(E/I)**	Grafix core, per sq cm
	Q4133 **(E/I)**	Grafix prime, per sq cm
	Q4134 **(E/I)**	Hmatrix, per sq cm
	Q4135 **(E/I)**	Mediskin, per sq cm
	Q4136 **(E/I)**	Ez-derm, per sq cm
ICD9:	142.0	Malignant neoplasm of parotid gland
	174.0-174.9	Malignant neoplasm of female breast (code range)
	210.2	Benign neoplasm of major salivary glands
	233.0	Carcinoma in situ, breast
	235.0	Neoplasm of uncertain behavior of major salivary glands
	250.00-250.93	Diabetes mellitus (code range)
	440.23	Atherosclerosis of the extremities with ulceration
	440.24	Atherosclerosis of the extremities with gangrene
	443.9	Peripheral vascular disease, unspecified
	454.0	Varicose veins of lower extremities; with ulcer
	454.1	with inflammation
	454.2	with ulcer and inflammation
	527.0	Diseases of the salivary glands
	527.1	atrophy
	527.2	sialoadenitis
	527.3	abscess
	527.4	fistula
	527.5	sialolithiasis
	527.6	mucocele
	527.7	disturbance of salivary secretion
	527.8	other specified diseases of the salivary glands
	527.9	unspecified disease of the salivary glands

	707.13	Ulcer of ankle
	707.14	Ulcer of heel, midfoot
	707.15	Ulcer of other part of foot
	948.00 - 948.99	Burns classified according to extent of body surface involved (code range)
	949.3	Full-thickness skin loss (third degree NOS)
	949.4	Deep necrosis of underlying tissues [deep third degree] without mention of loss of body part
	949.5	Deep necrosis of underlying tissues [deep third degree] with loss of a body part
	V10.3	Personal history of malignant neoplasm; breast
	V45.71	Acquired absence of breast and nipple
ICD10:	C07	Malignant neoplasm of parotid gland
	C50.011-C50.019	Malignant neoplasm of nipple and areola, right female breast (code range)
	C50.111-C50.119	Malignant neoplasm of central portion of female breast (code range)
	C50.211-C50.219	Malignant neoplasm of upper-inner quadrant of female breast (code range)
	C50.311-C50.319	Malignant neoplasm of lower-inner quadrant of female breast (code range)
	C50.411-C50.419	Malignant neoplasm of upper-outer quadrant of female breast (code range)
	C50.511-C50.519	Malignant neoplasm of lower-outer quadrant of female breast (code range)
	C50.611-C50.619	Malignant neoplasm of axillary tail of female breast (code range)
	C50.811-C50.819	Malignant neoplasm of overlapping sites of female breast (code range)
	C50.911-C50.919	Malignant neoplasm of unspecified site of female breast (code range)
	D05.00-D05.92	Carcinoma in situ of breast (code range)
	D11.0-D11.9	Benign neoplasm of major salivary gland (code range)
	D37.030-D37.039	Neoplasm of uncertain behavior of the salivary glands (code range)
	E10.10-E10.69	Type 1 diabetes mellitus with specified complication (code range)
	E11.00-E11.8	Type 2 diabetes mellitus with specified complication (code range)
	E11.9	Type 2 diabetes mellitus without complications
	E13.00-E13.9	Other specified diabetes mellitus with specified complication (code range)
	E13.9	Other specified diabetes mellitus without complications
	I70.232-I70.269	Atherosclerosis of native arteries (code range)
	I70.333-I70.744	Atherosclerosis of bypass graft(s) (code range)
	I83.003-I83.005	Varicose veins of unspecified lower extremity with ulcer (code range)
	I83.011-I83.022	Varicose veins of lower extremity with ulcer (code range)
	I83.029	Varicose veins of left lower extremity with ulcer of unspecified site
	I83.10-I83.12	Varicose veins of lower extremity with inflammation (code range)

I183.201-I83.202	Varicose veins of unspecified lower extremity with both ulcer and inflammation (code range)
I83.205-I83.228	Varicose veins of lower extremity with both ulcer and inflammation (code range)
K11.1-K11.9	Disease of salivary gland (code range)
L97.301-L97.303	Non-pressure chronic ulcer of unspecified ankle (code range)
L97.311-L97.329	Non-pressure chronic ulcer of ankle (code range)
L97.401-L97.409	Non-pressure chronic ulcer of unspecified heel and midfoot (code range)
L97.413-L97.429	Non-pressure chronic ulcer of heel and midfoot (code range)
L97.501-L97.529	Non-pressure chronic ulcer of other part of foot (code range)
R68.2	Dry mouth, unspecified
T30.0	Burn of unspecified body region, unspecified degree
T30.4	Corrosion of unspecified body region, unspecified degree
T31.0-T31.99	Burns (code range)
T32.0-T32.99	Corrosions (code range)
Z85.3	Personal history of malignant neoplasm of breast
Z90.10-Z90.13	Acquired absence of breast and nipple (code range)

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KEY WORDS:

AlloDerm®, AlloMax™, AlloSkin™, Apligraf®, ArthroFlex™, Artificial skin, Avaulta Plus™, Biobrane®, Biobrane l®, Bioengineered skin, Biologic tissue, Collamend, Conexa™, Cymetra®, Dermagraft®, DermaMatrix, DermaSpan™, Endoform Dermal Template™, ENDURAgen™, Epicel®, EpiFix, E-Z Derm™, FlexHD®, GammaGraft, Grafix® CORE, Grafix® PRIME, GraftJacket®, GraftJacket® Xpress, Graftskin, hMatrix®, Hyalomatrix®, Integra™, Integra™ Bilayer Wound® Matrix, Integra™ Dermal Regeneration Matrix®, Integra™ Flowable Wound® Matrix, IntegуPly™, Laserskin, Matristem® Micromatrix, Matristem® Wound Matrix, Matristem® Burn Matrix, Mediskin®, Neoform, OASIS® Wound Matrix, OASIS® Burn Matrix, OASIS® Ultra, Orcel™, Orthoadapt, Pelvicol, Pelvisoft, Permacol™, Primatrix, Restore, Skin substitute, StrataGraft, Strattice™, SurgiMend®, TheraSkin®, Tissuemend, TranCyte™, TranZgraft, Unite™ Biomatrix, Veritas® Collagen Matrix.

CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS

There is currently a Local Coverage Determination (LCD) for Biologic Products for Wound Treatment and Surgical Interventions. There are several articles listed on the LCD that address CMS coverage of specific products. Please refer to the following website for Medicare Members: http://apps.ngsmedicare.com/lcd/LCD_L26003.htm.