

Policy: MP075

Section: Medical Benefit Policy

Subject: Tissue Engineered Skin Substitutes

Applicable Lines of Business

Commercial	X	CHIP	X
Medicare	X	ACA	X
Medicaid	X		

I. Policy: Tissue Engineered Skin Substitutes

II. Purpose/Objective:

To provide a policy of coverage regarding

III. Responsibility:

- A. Medical Directors
- B. Medical Management

IV. Required Definitions

1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. Devised – the date the policy was implemented.
4. Revised – the date of every revision to the policy, including typographical and grammatical changes.
5. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

V. Additional Definitions

Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:

- a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- b. provided for the diagnosis, and the direct care and treatment of the Member's condition, illness disease or injury;
- c. in accordance with current standards of good medical treatment practiced by the general medical community.
- d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and
- e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

Medicaid Business Segment

Medically Necessary — A service, item, procedure, or level of care that is necessary for the proper treatment or management of an illness, injury, or disability is one that:

- Will, or is reasonably expected to, prevent the onset of an illness, condition, injury or disability.
- Will, or is reasonably expected to, reduce or ameliorate the physical, mental or developmental effects of an illness, condition, injury or disability.

- Will assist the Member to achieve or maintain maximum functional capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for Members of the same age

DESCRIPTION:

Tissue engineered skin substitutes have been developed to replace autografts, allografts and xenograft in the treatment of extensive burn injuries and hard-to-heal, chronic wounds associated with non-burn etiologies such as venous ulcers and diabetic foot ulcers. The goal of tissue engineered skin substitute therapy is to provide a temporary biologic dressing that encourages skin tissue regeneration and wound healing through its own natural contingent of growth factors and proteins. It delivers new cells to the wound, which are able to adjust to the microenvironment of the wound and stimulate healing.

INDICATIONS:

Tissue engineered skin substitutes may be considered **medically necessary** when used for the appropriate FDA approved indications. Specific criteria may also apply as listed below:

Apligraf® is a bilayered, living skin equivalent which is indicated for treatment of:

1. Venous insufficiency ulcers when **all** of the following criteria are met:

- The ulcer is a non-infected partial or full thickness ulcer at least 1.0cm² in size due to clinically documented venous insufficiency;
- The ulcer has been present for a minimum of 4 weeks, has been treated with conventional non-surgical therapy (including, but not limited to: debridement, off-loading, compression dressings, wet and/or dry dressings, cleansing and nutritional support) for at least 4 weeks and has failed to respond (e.g., no significant decrease in wound size, failure to show signs of granulation or progression toward closure).

2. Neuropathic diabetic foot ulcers when **all** of the following criteria are met:

- Physician documentation of medical management for clinically documented type 1 or type 2 diabetes
- The wound is a non-infected full thickness neuropathic diabetic foot ulcer and has been present for a minimum of 3 weeks and at least 1.0cm² in size due to clinically documented diabetic neuropathy
- The ulcer is located on the plantar, medial or lateral surface of the foot and is free of infection, tunnels, tracts, cellulitis, eschar or obvious necrotic material
- The ulcer extends through the dermis but does not involve the tendon, muscle, capsule or exposure to bone
- Conservative treatment measures including a non-weight bearing regimen, debridement and acceptable methods of wound care have been tried for a minimum of 3 weeks and there has been failure to respond to conservative measures
- The extremity is free of Charcot's arthropathy
- There is adequate arterial blood supply to support tissue growth

Dermagraft® is a cryopreserved dermal substitute derived from human fibroblasts and is indicated for the treatment of diabetic foot ulcers when **all** of the following criteria are met:

- Physician documentation of medical management for clinically documented type 1 or type 2 diabetes
- The wound is a non-infected full thickness diabetic foot ulcer and has been present for a minimum of 3 weeks and at least 1.0cm² in size
- The ulcer is located on the plantar, medial or lateral surface of the foot and is free of infection, tunnels, tracts, cellulitis, eschar or obvious necrotic material
- The ulcer extends through the dermis but does not involve the tendon, muscle, capsule or exposure to bone
- Conservative treatment measures including a non-weight bearing regimen, debridement and acceptable methods of wound care have been tried for a minimum of 3 weeks and there has been failure to respond to conservative measures.
- The extremity is free of Charcot's arthropathy
- There is adequate arterial blood supply to support tissue growth

Biobrane® (biosynthetic dressing) is a knitted nylon fabric bonded to an ultra-thin silicone rubber membrane coated with a protein (gelatin) and is indicated for the treatment of thermal injuries, superficial scald burn or flame injury of the hand when:

- The burn is superficial, partial-thickness with limited involvement of the dermis (less than or equal to 25% total body surface area); **and**
- The burn is clean, non-infected, and free of nonviable tissue and coagulation eschar.

Orcel® is an absorbable bilayered cellular matrix, made of bovine collagen, in which human dermal cells have been cultured and is considered medically necessary for the treatment of

- healing donor site wounds in burn victims, and
- for use in persons with dystrophic epidermolysis bullosa undergoing hand reconstruction surgery to close and heal wounds created by the surgery, including those at donor sites when used in accordance with the FDA's Humanitarian Device Exemption.

TransCyte® consists of human dermal fibroblasts grown on nylon mesh, combined with a synthetic epidermal layer and is considered medically necessary for

- the temporary wound covering for surgically excised full-thickness and deep partial-thickness thermal burn wounds in persons who require such a covering before autograft placement.

Integra® Dermal Regeneration Template, Matrix Wound Dressing, Bilayer Matrix Wound Dressing, and Meshed Bilayer Wound Matrix an acellular, biodegradable copolymer matrix coated is considered medically necessary for post-excision treatment of full thickness of deep partial thickness burns when autografting is not feasible due to the lack of suitable healthy tissue or the member's weak physiological state.

Alloderm® (acellular dermal matrix allograft) is considered medically necessary when used

- In association with a covered, medically necessary breast reconstruction procedure.
- Surgical repair of complex abdominal wall wounds (e.g., due to infection, fascial defect, etc.)
- ENT/Head & Neck reconstructive procedures

Neoform® (solvent-dehydrated, gamma-irradiated preserved human allograft) is considered medically necessary when used in association with a covered, medically necessary breast reconstruction procedure.

AlloMax™ is considered medically necessary when used in association with a covered, medically necessary breast reconstruction procedure.

Oasis® Wound Matrix is considered medically necessary when used to treat the following:

1. Partial or full thickness venous insufficiency or diabetic ulcers of the lower extremity when the following criteria are met:
 - The ulcer has been present for a minimum of 4 weeks,
 - has been treated with conventional non-surgical therapy (including, but not limited to: debridement, off-loading, compression dressings, wet and/or dry dressings, cleansing and nutritional support) for at least 4 weeks and
 - has failed to respond (e.g., no significant decrease in wound size, failure to show signs of granulation or progression toward closure).
2. Pressure ulcers
3. Surgical or traumatic wounds
4. Draining wounds

Epicel® is considered medically necessary when used for the treatment of deep dermal or full thickness burns of 30% or more of the total body surface area in accordance with the FDA's Humanitarian Device Exemption

Graftjacket® Regenerative Tissue Matrix is considered medically necessary when used for the treatment of diabetic foot ulcers when the following criteria are met:

- Physician documentation of medical management for clinically documented type 1 or type 2 diabetes
- The wound is a non-infected full thickness neuropathic diabetic foot ulcer and has been present for a minimum of 3 weeks and at least 1.0cm² in size due to clinically documented diabetic neuropathy
- The ulcer is located on the plantar, medial or lateral surface of the foot and is free of infection, tunnels, tracts, cellulitis, eschar or obvious necrotic material
- The ulcer extends through the dermis but does not involve the tendon, muscle, capsule or exposure to bone
- Conservative treatment measures including a non-weight bearing regimen, debridement and acceptable methods of wound care have been tried for a minimum of 3 weeks and there has been failure to respond to conservative measures
- The extremity is free of Charcot's arthropathy
- There is adequate arterial blood supply to support tissue growth

Any tissue engineered skin substitute not specifically addressed in this document should be considered as requiring prior authorization.

CONTRAINDICATIONS:

- Clinically infected wounds
- Ulcers with sinus tracts
- Known allergies to bovine collagen
- Apligraf and Dermagraft are not approved for use in the treatment of acute surgical wounds, pressure sores or burns.

LIMITATIONS:

For the purpose of this policy, re-application is referring to an additional application of skin substitutes to the same ulcer within the same treatment period. Re-treatment is referencing a new treatment period where the same ulcer is being treated again because the initial treatment has most likely failed.

For Apligraf the following limitations apply and will be considered NON-COVERED as being not medically necessary:

- The efficacy of treatment with Apligraf beyond five applications at no less than weekly intervals has not been established.
- Reapplication when initial application has resulted in no measurable response
- Retreatment within 1 year following the last successful application
- Retreatment following unsuccessful treatment defined for the purposes of this policy as 5 failed Apligraf applications

For Dermagraft: The following limitation applies and will be considered NON-COVERED as being not medically necessary:

- Retreatment within 1 year following the last successful application
- Reapplication when initial application has resulted in no measurable response
- Retreatment of an ulcer following the unsuccessful treatment where it consisted of 8 failed Dermagraft® applications

Data regarding Permacol™ Biologic porcine mesh implant is limited to small case series, retrospective case reviews, and non-randomized comparison studies. There is minimal evidence in the peer-reviewed, medical literature of its effectiveness as an alternative to synthetic meshes, that it provides any advantage over other available surgical mesh, and information on the potential complications associated with its use is lacking. Requests for this product will be considered on a “per case” basis.

The use of the following products or any FDA-approved product not listed is limited to the FDA approved indication.

AlloDerm® RTM Ready to Use	Conexa™	Integra™ Matrix Wound	Repriza™
AlloMax™	CorMatrix®	InteguPly™	Restore® Orthobiologic
AlloMend™	CRXa™	Jaloskin®	Seamguard®
Allopatch HD	CryoSkin®	LiquidGen™	SportMesh™
Alloskin™	Cuffpatch™	MariGen Omega3	SS Matrix™
Alloskin RT™	Cymetra	Matriderm®	Stimulen™ Collagen
AlloWrap®	DeNovo® NT Graft	Matristem®	StrataGraft®
AmnioCare®	Dermacell™	Matrix HD™	Strattice™
AmnioExcel™	Dermadapt™ Wound Dressing	MediHoney®	Suprathel®
AmnioFix™	DermaMatrix™	Medeor™	SurgiMend®
Amniomatrix™	DermaSpan™	Mediskin®	Surgisis® (including Surgisis® AFP™ Anal Fistula Plug, Surgisis® Gold™ Hernia Repair Grafts, and Surgisis™)
AmnioMTM™	DressSkin™	Memoderm™	Talymed™

AmnioShield®	Duraform™	Menaflex™	TenoGlide™
Aongen™ Collagen Matrix	Duragen® XS	Meso BioMatrix™	TenSIX™
Architect Extracellular Matrix™	Duragen™ Plus	Neoform Dermis™	TheraForm™ Standard/Sheet
ArthroFlex®	DuraMatrix™	NEOX® 100 Quick-Peel	TissueMend®
Atlas Wound Matrix	Durepair® Regeneration Matrix	NEOX® 1k Wound Matrix	TranzGraft®
Avance® Nerve Graft	Endobon® Xenograft Granules	NEOX® FLO NuCel™	Unite™
Avaulta Plus™	Endoform™	Neuragen®	Veritas® Collagen Matrix
AxoGuard® nerve connector	ENDURAgen™	NeuraWrap™	X-Repair
AxoGuard® nerve protector	Epicel®	Neuroflex™	XCM Biologic™
Biobrane®	EpiDex®	NeuroMatrix™	Xelma®
BioDDryFlex®	EpiFix™	NeuroMend™	XenMatrix™
Biodesign	Excellagen®	NuCel®	Xwrap™ (Hydro, DRY, and ECM)
BioDExCel™	EZ Derm™	NuShield®	TheraSkin®
BioDfactor™	FlexHD® Required Program Exception for Medicaid	Oasis™	Amniply
BioDfence®	FloGraft™	OrthADAPT™	Reguard
BioDOptix™	FortaDerm™ Wound Dressing	OsseoGuard®	Cortiva
BioFiber™	Gammagraft™	Ovation®	AllopatchHD Required Program Exception for Medicaid
Biovance®		Puraply	AmnioBand Required Program Exception for Medicaid
C-QUR™	GORE®Bio –A	Pelvicol®	Guardian Required Program Exception for Medicaid
Celaderm	Grafix® CORE	Pelvisoft®	
CellerateRX®	Grafix® PRIME	Peri-Guard® Repair Patch	
CelluTome™	GraftJacket™	Peri-Strips Dry®	
CLARIX™ 100 Quick-Peel	Graftjacket™ Xpress injectable	Permacol™	
CLARIX™ 1k	HA Absorbent Wound Dressing	PriMatrix®	
CLARIX™ FLO	Helicoll	Promogran™	
CollaFix™	hMatrix®	PTFE felt	
Collamend™	Hyalomatrix®	Puracol®	
CollaSorb™	Inforce®	Puros® Dermis	
CollaWound™	Integra® Dermal Regeneration	Repliform®	

FOR MEDICAID BUSINESS SEGMENT:

Epifix (Q4186), Grafix Core (Q4132) and Grafix Prime (Q4133) require a program exception to be considered for coverage

Amnioband (Q4151), Guardian (Q4151) FlexHD (Q4128) and Allopatch(Q4128) require a program exception to be considered for coverage

Other Associated Key Words:

Human Skin Equivalents

EXCLUSIONS:

The use of tissue engineered skin equivalents in any application outside of the current FDA approvals is considered **experimental, investigational or unproven** and is **NOT COVERED**.

Medicaid Business Segment:

Any requests for services, that do not meet criteria set in the PARP, may be evaluated on a case by case basis.

Note: A complete description of the process by which a given technology or service is evaluated and determined to be experimental, investigational or unproven is outlined in MP 15 - Experimental Investigational or Unproven Services or Treatment.

CODING ASSOCIATED WITH:

The coding listed in this document may not represent the comprehensive range of codes that may be associated with this service.

HCPCS CODES:

- 15150 Tissue cultured skin autograft, trunk, arms, legs; first 25 sq. cm or less
- 15151 Tissue cultured skin autograft, trunk, arms, legs; additional 1 sq. cm to 75 sq. cm
- 15152 Tissue cultured skin autograft, trunk, arms, legs; each additional 100 sq. cm, or each additional 1% of body area of infants and children, or part thereof
- 15155 Tissue cultured skin autograft, face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits; first 25 sq. cm or less
- 15156 Tissue cultured skin autograft, face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits; additional 1 sq. cm to 75 sq. cm
- 15157 Tissue cultured skin autograft, face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits; each additional 100 sq. cm, or each additional 1% of body area of infants and children, or part thereof
- 15271 application of skin substitute graft to trunk, arms, legs, total wound surface area up to 100 sq. cm; first 25 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% of 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 infants and children
- 15278 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
- 15777 Implantation of biologic implant (eg, acellular dermal matrix) for soft tissue reinforcement (eg, breast, trunk)
- A2001 Innovamatrix ac, per square centimeter
- A2002 Mirragen advanced wound matrix, per square centimeter
- A2003 bio-connekt wound matrix, per square centimeter
- A2004 Xcellistem, 1mg
- A2005 Microlyte matrix, per square centimeter
- A2006 Novosorb synpath dermal matrix, per square centimeter
- A2007 Restrata, per square centimeter
- A2008 Theragenesis, per square centimeter
- A2009 Symphony, per square centimeter
- A2010 Apis, per square centimeter
- A2022 InnovaBurn or InnovaMatrix XL, per sq cm
- A2023 InnovaMatrix PD, 1 mg
- A2024 Resolve Matrix, per sq cm
- A2025 Miro3D, per cu cm
- C9352 Microporous collagen implantable tube (NeuraGen Nerve Guide), per centimeter length
- C9353 Microporous collagen implantable slit tube (NeuraWrap Nerve Protector), per centimeter length

C9354 Acellular pericardial tissue matrix of non-human origin (Veritas), per square centimeter
C9355 Collagen nerve cuff (NeuroMatrix), per 0.5 centimeter length
C9356 Tendon, porous matrix of cross-linked collagen and glycosaminoglycan matrix (TenoGlide Tendon Protector Sheet), per square centimeter
C9358 Dermal substitute, native, non-denatured collagen, fetal bovine origin (SurgiMend Collagen Matrix), per 0.5 square centimeters
C9359 Porous purified collagen matrix bone void filler (integra mozaik osteoconductive scaffold putty, integra osteoconductive scaffold putty), per 0.5cc
C9360 Dermal substitute, native, non-denatured collagen, neonatal bovine origin (SurgiMend Collagen Matrix), per 0.5 square centimeters
C9361 Collagen matrix nerve wrap (NeuroMend Collagen Nerve Wrap), per 0.5 centimeter length
C9362 Porous purified collagen matrix bone void filler (integra mozaik osteoconductive scaffold strip), per 0.5 cc
C9363 Skin substitute, Integra Meshed Bilayer Wound Matrix, per square centimeter
C9364 Porcine implant, Permacol, per square centimeter
G0428 Collagen meniscus implant procedure for filling meniscal defects (e.g., CMI, collagen scaffold, Menaflex)
Q4100 Skin substitute, not otherwise classified [when specified as TransCyte]
Q4101 Apligraf, per square cm
Q4102 Skin substitute, Oasis wound matrix, per sq. cm
Q4103 Oasis Burn Matrix, per square centimeter
Q4104 Integra Bilayer Matrix Wound Dressing (BMWWD), per square centimeter
Q4105 Integra Dermal Regeneration Template (DRT), per square centimeter
Q4106 Dermagraft, per square centimeter
Q4107 Graftjacket, per square centimeter
Q4108 Integra Matrix, per square centimeter
Q4110 PriMatrix, per square centimeter
Q4111 Gammagraft, per square centimeter
Q4112 Cymetra, injectable, 1 cc
Q4113 Graftjacket Xpress, injectable, 1 cc
Q4114 Integra Flowable Wound Matrix, injectable, 1 cc
Q4115 Alloskin, per square centimeter
Q4116 Skin substitute, AlloDerm, per square centimeter
Q4117 Hyalomatrix, per square centimeter
Q4118 Matristem micromatrix, 1 mg
Q4121 Theraskin, per square centimeter
Q4122 Dermacell, per square centimeter
Q4123 AlloSkin RT, per square centimeter
Q4124 Oasis Ultra Tri-Layer Wound Matrix, per square centimeter
Q4125 ArthroFlex, per square centimeter
Q4126 Memoderm, dermaspan, transgraft or integuply, per square centimeter
Q4127 Talymed, per square centimeter
Q4128 FlexHD, AlloPatch HD, or Matrix HD, per square centimeter
Q4130 Strattice, per square centimeter
Q4131 EpiFix, per square centimeter
Q4132 Grafix CORE, per square centimeter
Q4133 Grafix PRIME, per square centimeter
Q4134 hMatrix, per square centimeter
Q4135 Mediskin, per square centimeter
Q4136 EZ-derm, per square centimeter
Q4137 Amnioexcel or biodexcel, per square centimeter
Q4138 Biodfence dryflex, per square centimeter
Q4139 Amniomatrix or biodmatrix, injectable, 1 cc
Q4140 Biodfence, per square centimeter
Q4141 Alloskin ac, per square centimeter
Q4142 Xcm biologic tissue matrix, per square centimeter
Q4143 Repriza, per square centimeter
Q4145 Epifix, injectable, 1 mg
Q4146 Tensix, per square centimeter
Q4147 Architect extracellular matrix, per square centimeter
Q4148 Neox 1k, per square centimeter
Q4149 Excellagen, 0.1 cc
Q4150 Allowrap DS or Dry, per square centimeter
Q4151 AmnioBand or Guardian, per square centimeter

Q4152 DermaPure, per square centimeter
Q4153 Dermavest, per square centimeter
Q4154 Biovance, per square centimeter
Q4155 NeoxFlo or ClarixFlo, 1 mg
Q4156 Neox 100, per square centimeter
Q4157 Revitalon, per square centimeter
Q4158 MariGen, per square centimeter
Q4159 Affinity, per square centimeter
Q4160 NuShield, per square centimeter
Q4161 Bio-connekt wound matrix, per square centimeter
Q4162 Amniopro flow, bioskin flow, biorenew flow, woundex flow, amniogen-a, amniogen-c, 0.5cc
Q4163 Amniopro, bioskin, biorenew, woundex, amniogen-45, amniogen-200, per square centimeter
Q4164 Helicoll, per square centimeter
Q4165 Keramatrix, per square centimeter
Q4166 Cytal, per square centimeter
Q4167 Truskin, per square centimeter
Q4168 Amnioband, 1 mg
Q4169 Artacent wound, per square centimeter
Q4170 Cygnus, per square centimeter
Q4171 Interfyl, 1 mg
Q4172 Puraply or puraply am, per square centimeter
Q4173 Palingen or palingen xplus, per square centimeter
Q4174 Palingen or promatrix, 0.36 mg per 0.25 cc
Q4175 Miroderm, per square centimeter
Q4176 Neopatch, per square centimeter
Q4177 Floweramnioflo, 0.1 cc
Q4178 Floweramniopatch, per square centimeter
Q4179 Flowerderm, per square centimeter
Q4180 Revita, per square centimeter
Q4181 Amnio wound, per square centimeter
Q4182 Transcyte, per square centimeter
Q4195-Q4197 Puraply
Q4249 Amniply, for topical use only, per square centimeter
Q4255 Reguard, for topical use only, per square centimeter
Q4285 NuDYN DL or NuDYN DL MESH, per sq cm
Q4286 NuDYN SL or NuDYN SLW, per sq cm

LINE OF BUSINESS:

Eligibility and contract specific benefits, limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy. For Medicare, applicable LCD's and NCD's will supercede this policy. For PA Medicaid Business segment, this policy applies as written.

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ECRI. AlloDerm Regenerative Tissue Matrix (AbbVie, Inc.) for Reconstructing Breast Tissue. 2020 Nov 30

ECRI. Skin Substitutes for Treating Diabetic Foot Ulcers in Patients Aged 65 Years or Older. 2021 Jan 25.

ECRI. Dermacell AWM (LifeNet Health Bio-Implants Division) for Chronic Wounds. 2020 Dec 18

This policy will be revised as necessary and reviewed no less than annually.

Devised: 6/02

Revised: 6/03 (Coding), 6/04; 6/05 (Coding); 03/06 (additional criteria, coding); 04/07; 2/08 (criteria); 2/09 (criteria); 4/10 (criteria); 7/11 (contradiction, exclusions, coding); 4/12 (indications, coding, references), 2/14 (indication, reference, removed exclusion); 2/15 Add Product names – remove PA requirement); 1/17 (add products, remove exclusions); 2/18 (reformat document); 11/19 (add Medicaid limitation); 11/20 (add products); 11/22 (clarify coverage of general products); 11/23 (added product restrictions)

Reviewed: 4/13, 3/16, 2/19, 11/21

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