“What’s New” Medical Policy Updates December 2025

Listed below are the recent changes made to policies within the Geisinger Health Plan Medical Policy Portfolio during the month of November that will become **effective January 15, 2026** (unless otherwise specified). The Plan uses medical policies as guidelines for coverage decisions made within members written benefit documents. Coverage may vary by line of business and providers and members are encouraged to verify benefit questions regarding eligibility before applying the terms of the policy.

MP056 Management of Excessive Skin and Subcutaneous Tissue – Revised – Add Indication

If the member has had bariatric surgery, they are at least 12 months post-operative and have documented stable weight for at least 3 months

Suction lipectomy (15876 – 15879) may be considered medically necessary for treatment of pain and disability from lipedema who have failed to respond to six or more months of conservative management (compression or manual therapy) lipedema when all of the following criteria are met:

- documentation of pain and hypersensitivity to touch in lipedema affected areas;
- functional impairments due to pain and/or mechanical restriction due to increased lipedema tissue;
- history of bruising without apparent cause in lipedema affected areas;
- lack of effect of weight loss on lipedema affected areas;
- tenderness and nodularity of fat deposits in lipedema affected areas

EXCLUSIONS:
Members may **NOT** be eligible for surgical management of excessive skin and subcutaneous tissue for any indications other than those listed above, including but not limited to:

- Restorative or reconstructive surgery performed for cosmetic purposes and from which no significantly improved physiologic function as determined by the Plan is anticipated, is **NOT COVERED**.

- Repair of a diastasis, defined as a thinning of the anterior abdominal wall fascia, in the absence of a true midline (ventral) hernia, is not considered medically necessary because it is not associated with conditions of clinical significance.

- Solely to treat back pain, or when performed in conjunction with abdominal or gynecological procedures (e.g. abdominal hernia repair, hysterectomy), unless the above criteria for panniculectomy or abdominoplasty are met separately.

The Plan does not provide coverage for abdominal suction-assisted lipectomy or liposuction not meeting specific criteria because it is considered cosmetic and **NOT COVERED.**

MP071 Continuous Subcutaneous Glucose Monitor (CSGM) – Revised – Add I-CGM Coverage

Implantable Real Time Continuous Glucose Monitoring (CGM) System (e.g., Eversense) (0446T – 0448T)

Implantable real-time CGM is considered medically necessary as an adjunct to self-monitoring of blood glucose for managing Type 1 diabetes mellitus (DM) or insulin-dependent Type 2 DM in individuals age 18 and older, with or without use of an external insulin pump.

Please see: Local Coverage Determination (LCD): Glucose Monitors (L33822) Noridian Healthcare Solutions, LLC (16013 - DME MAC, J-A) https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?LCDId=33822

and Glucose Monitor - Policy Article (A52464) https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleId=52464; and L38617 Implantable Continuous Glucose Monitors (I-CGM) https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=38617&ver=31

EXCLUSIONS:
The GlucoWatch® is an external device worn like a wristwatch that measures glucose every 20 minutes in interstitial fluid extracted through the skin with an electric current (referred to as reverse iontophoresis). Use of a non-implanted, external device (e.g., GlucoWatch®) in the monitoring of glucose levels in the interstitial fluid as a technique of diabetic monitoring, is considered **unproven** because there is insufficient evidence in the peer reviewed medical literature to support its reliability and efficacy. Therefore, it is **NOT COVERED**.

~~Unless otherwise mandated, CGM using an implantable glucose sensor (e.g., Eversense) is considered **unproven** because there is insufficient evidence in the peer reviewed medical literature to support its reliability and efficacy. Therefore, it is **NOT COVERED**~~

MP075 Tissue Engineered Skin Substitutes – Revised – Revise Product Approvals

Treatment of Diabetic Foot Ulcers or Venous Leg Ulcers

For MEDICARE Business Segment, please see: L35041 Skin Substitute Grafts/Cellular and Tissue-Based Products for the Treatment of Diabetic Foot Ulcers and Venous Leg Ulcers

For COMMERCIAL and NON-MEDICARE Business Segments:

INDICATIONS:
Tissue engineered skin substitutes, cellular and tissue-based products may be considered **medically necessary** ~~when used~~ for the treatment of diabetic foot ulcers or venous leg ulcers when the following criteria are met:

1. A chronic, non-infected diabetic foot ulcers that fail to achieve at least 50% ulcer area reduction after four weeks of standard care; OR
2. a chronic, non-infected venous leg ulcers that fail to respond after four weeks of standard care treatment.

Standard of Care treatment includes:

- Comprehensive assessment (history, exam, vascular assessment) and diagnostic tests as indicated
- For members with a diabetic foot ulcer: assessment of Type 1 or Type 2 diabetes and management history with attention to comorbidities, review of current blood glucose levels/hemoglobin A1c (HbA1c), diet and nutritional status, activity level, physical exam that includes assessment of skin, ulcer, and vascular perfusion and assessment of off-loading devices or use of appropriate footwear
- For members with a venous leg ulcer: assessment of clinical history (including prior ulcers, body mass index, history of pulmonary embolism or superficial/deep venous thrombosis), physical exam, evaluation of venous reflux, perforator incompetence, and venous thrombosis. The use of a firm strength compression garment (>20 mmHg) or multi-layered compressive dressing

Upon request, the following information must be available:

1. An implemented treatment plan to be continued throughout the course of treatment demonstrating all the following:
   - Debridement to a clean granular base.
   - Documented evidence of offloading for diabetic foot ulcer.
   - Documented evidence of sustained compression therapy for venous leg ulcer.
   - Infection control
   - Management of exudate with maintenance of a moist environment.
   - Documentation of smoking history, and counselling on the effect of smoking on wound healing. Treatment for smoking cessation and outcome of counselling (if applicable).

2. Documentation of response to treatment requires measurements of the initial ulcer, pre-treatment ulcer measurements, weekly ulcer measurements, post-completion ulcer measurements following (at least) 4 weeks of standard treatment, ulcer measurements at initial placement of the skin substitute graft/CTP, and before each subsequent placement of the skin substitute graft/CTP.
3. Failure to heal or stalled response despite standard of care measures must have preceded the application for a minimum of 4 weeks and established standard treatment must continue for the course of therapy. Continuous compression therapy for venous leg ulcers must be documented for the episode of care.
4. Documentation must include the interventions having failed during prior ulcer evaluation and management. The record must include an updated medication history, review of pertinent medical problems diagnosed since the previous ulcer evaluation, and explanation of the planned skin replacement with choice of skin substitute graft/CTP.
5. The member is under the care of a qualified provider for the treatment of the underlying systemic disease process(es) (e.g., venous insufficiency, diabetes, neuropathy)

The following products are covered for treatment of diabetic foot ulcers:

Affinity	**Q4159**
AmnioBand, guardian	**Q4151 AmnioBand Requires Program Exception for Medicaid**
Apligraf	**Q4101**
DermACELL, awm, porous	**Q4122**
Derma-Gide	**Q4203**
Dermagraft	**Q4106**
Epicord	**Q4187**
Epifix	**Q4186**
FlexHD or AllopatchHD	**Q4128 FlexHD® Requires Program Exception for Medicaid**
Grafix stravix prime pl	**Q4133**
GraftJacket	**Q4107**
Integra or Omnigraft dermal regeneration template	**Q4105**
Kerecis Omega3/Kerecis omega3, MariGen shield	**A2019, Q4158 Kerecis Omega3 MariGen Shield Requires Program Exception for Medicaid**
NuShield	**Q4160**
Oasis wound matrix	**Q4102**
PriMatrix	**Q4110**
Theraskin	**Q4121**

E08.621*	Diabetes mellitus due to underlying condition with foot ulcer
E09.621*	Drug or chemical induced diabetes mellitus with foot ulcer
E10.621*	Type 1 diabetes mellitus with foot ulcer
E11.621*	Type 2 diabetes mellitus with foot ulcer
E13.621*	Other specified diabetes mellitus with foot ulcer

The following products are covered for treatment of venous leg ulcers:

AmnioBand, guardian	**Q4151 AmnioBand Requires Program Exception for Medicaid**
Apligraf	**Q4101**
Dermagraft	**Q4106**
Epifix	**Q4186**
Oasis wound matrix	**Q4102**

I83.011* Varicose veins of right lower extremity with ulcer of thigh
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
I83.021* Varicose veins of left lower extremity with ulcer of thigh
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
I83.211* Varicose veins of right lower extremity with both ulcer of thigh and inflammation
I83.212* Varicose veins of right lower extremity with both ulcer of calf and inflammation
I83.213* Varicose veins of right lower extremity with both ulcer of ankle and inflammation
I83.214* Varicose veins of right lower extremity with both ulcer of heel and midfoot and inflammation
I83.215* Varicose veins of right lower extremity with both ulcer other part of foot and inflammation
I83.218* Varicose veins of right lower extremity with both ulcer of other part of lower extremity and inflammation
I83.221* Varicose veins of left lower extremity with both ulcer of thigh and inflammation
I83.222* Varicose veins of left lower extremity with both ulcer of calf and inflammation
I83.223* Varicose veins of left lower extremity with both ulcer of ankle and inflammation
I83.224* Varicose veins of left lower extremity with both ulcer of heel and midfoot and inflammation
I83.225* Varicose veins of left lower extremity with both ulcer other part of foot and inflammation
I83.228* Varicose veins of left lower extremity with both ulcer of other part of lower extremity and inflammation
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
I87.031* Postthrombotic syndrome with ulcer and inflammation of right lower extremity
I87.032* Postthrombotic syndrome with ulcer and inflammation of left lower extremity
I87.033* Postthrombotic syndrome with ulcer and inflammation of bilateral 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
I87.331* Chronic venous hypertension (idiopathic) with ulcer and inflammation of right lower extremity
I87.332* Chronic venous hypertension (idiopathic) with ulcer and inflammation of left lower extremity
I87.333* Chronic venous hypertension (idiopathic) with ulcer and inflammation of bilateral lower extremity

LIMITATIONS:
Liquid or gel preparations are not considered grafts.

EXCLUSIONS:
The use of tissue engineered skin equivalents not specifically listed for use in diabetic foot ulcers or venous leg ulcers ~~or in any application outside of the current FDA approvals~~ is considered ~~**experimental, investigational or**~~ **unproven** and is **NOT COVERED**

Treatment of Burns and Surgical Wound/Reconstruction:

Tissue engineered skin substitutes, cellular and tissue-based products may be considered **medically necessary** ~~when used~~ for the treatment of burns and surgical wounds/reconstruction when the following criteria are met:

Biobrane® (Q4100) (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® (C9200) 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® (Q4182) 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 (Q4104 – Q4108) 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® (Q4116) (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® (Q4100) (solvent-dehydrated, gamma-irradiated preserved human allograft) is considered medically necessary when used in association with a covered, medically necessary breast reconstruction procedure.

AlloMax™ (Q4100) is considered medically necessary when used in association with a covered, medically necessary breast reconstruction procedure.

Epicel® (Q4100) 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

NeuraGen (C9352) and NeuroMatrix (C9355) for the repair and closure of peripheral nerve gaps may be considered medically necessary in all of the following scenarios

- conduit-assisted repair as a technique for tension-relief at the peripheral nerve repair site or major nerve with a gap not exceeding 6 mm
- repair of digital nerve injuries with gaps less than 15 mm
- repair of digital nerve injuries with gaps 15-25 mm, where allograft nerve is not available
- repair of major nerves with small gaps not exceeding 6 mm, where allograft nerve is not available

EXCLUSIONS:

The use of tissue engineered skin equivalents and wound products not specifically listed under Indications ~~or in any application outside of the current FDA approvals~~ is considered ~~**experimental, investigational or**~~ **unproven** and is **NOT COVERED.**

~~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 1.0cm^2 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 1.0cm^2 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 1.0cm^2 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 1.0cm^2 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.

Repliform®	Conexa™	Hyalomatrix®	Repriza™
Puros® Dermis	CorMatrix®	IntéguPly™	Restore® Orthobiologic
AlloMend™	CRXa™	Jaloskin®	Seamguard®
Puracol®	CryoSkin®	LiquidGen™	SportMesh™
Alloskin™	Cuffpatch™	MariGen Omega3	SS Matrix™
Alloskin RT™	Cymetra	Matriderm®	Stimulen™ Collagen
AlloWrap®	DeNovo® NT Graft	Matristem®	StrataGraft®
AmnioCare®		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		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	Inforce®	Neuroflex™	XCM Biologic™
CollaFix™	EpiDex®	NeuroMatrix™	Xelma®
BioDDryFlex®		NeuroMend™	XenMatrix™
Biodesign	Excellagen®	NuCel®	Xwrap™ (Hydro, DRY, and ECM)
BioDExCel™	EZ Derm™	Collamend™	hMatrix®
BioDfactor™	CollaWound™	CollaSorb™	Amniply
BioDfence®	FloGraft™	OrthADAPT™	Reguard
BioDOptix™	FortaDerm™ Wound Dressing	OsseoGuard®	Cortiva
BioFiber™	Gammagraft™	Ovation®	AllopatchHD **Requires Program Exception for Medicaid**
Biovance®		Puraply	
C-QUR™	GORE®Bio –A	Pelvicol®	Guardian **Requires Program Exception for Medicaid**
Celaderm	Grafix® CORE	Pelvisoft®	PTFE felt
CellerateRX®	Grafix® PRIME	Peri-Guard® Repair Patch	Helicoll
CelluTome™	GraftJacket™	Peri-Strips Dry®	CLARIX™ FLO
CLARIX™ 100 Quick-Peel	Graftjacket™ Xpress injectable	Permacol™	Promogran™
CLARIX™ 1k	HA Absorbent Wound Dressing	Via Matrix	

EXCLUSIONS:
The use of tissue engineered skin equivalents not specifically listed in this policy for use in diabetic foot ulcers or venous leg ulcers or in any application outside of the current FDA approvals is considered ~~**experimental, investigational or**~~ **unproven** and is **NOT COVERED**.

~~**MEDICARE BUSINESS SEGMENT: please also see Novitas Solutions, Inc. LCD L35041**~~

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

Kerecis Omega3 (A2019) and Kerecis Omega3 MariGen Shield (Q4158) require a program exception to be considered for coverage.

~~**Other Associated Key Words:**~~
~~Human Skin Equivalents~~

MP184 Intracranial Percutaneous Transluminal Angioplasty – Revised – Add Indications

Angioplasty with or without stent placement may be considered medically necessary for the treatment of Idiopathic intracranial hypertension (IIH), also known as pseudotumor cerebri, when the following criteria are met:

- IIH diagnosis has been established; and
  - bilateral venous sinus stenosis, or
  - unilateral stenosis and contralateral hypoplasia;

  and
- member is refractory to or intolerant of maximum medical therapy

Endovascular intra-arterial mechanical embolectomy or thrombectomy may be considered medically necessary in the treatment of acute ischemic stroke when the following criteria have been met:

- Angiographic evidence of proximal arterial occlusion of the anterior circulation of the brain, involving any of the following anterior intracranial arteries:
  - Intracranial internal carotid; OR
  - Middle cerebral artery; OR
  - Anterior cerebral artery;

  AND
- Neuroimaging is consistent with early ischemic change, evidence of substantial and clinically significant neurologic deficits, and has ruled out intracranial hemorrhage or arterial dissection
- Intra-arterial mechanical embolectomy is performed within 12 hours of onset of symptoms

Extracranial-intracranial (EC-IC) arterial bypass surgery may be considered medically necessary for the following:

- Intracranial aneurysms unable to be treated without occlusion of the parent artery;
- Intracranial or transcranial carotid stenosis with evidence of flow-dependent ischemia documented by abnormal response to acetazolamide challenge, significantly elevated oxygen extraction fraction (OEF) on appropriate radiographic imaging;
- Ischemic Moyamoya disease;
- Tumors encasing or invading major cerebral arteries.

MEDICARE AND MEDICAID BUSINESS SEGMENT: See NCD 20.7 Percutaneous Transluminal Angioplasty

For Medicare and Medicaid Business Segment, intracranial percutaneous transluminal angioplasty with stenting may be considered medically necessary for the treatment of cerebral artery stenosis ≥50% in patients with intracranial atherosclerotic disease when furnished in accordance with the FDA-approved protocols governing Category-B Investigational Device Exemption (IDE) clinical trials.

~~**EXCLUSIONS:**~~

~~Although the device is FDA approved, there is insufficient evidence in the peer-reviewed published medical literature to establish the effectiveness of Intracranial Percutaneous Transluminal Angioplasty on health outcomes when compared to established treatments or technologies. For all lines of business **except Medicare and Medicaid** products, the use of Intracranial Percutaneous Transluminal Angioplasty with or without stenting, for the treatment of intracranial atherosclerotic disease and cerebral vasospasm after aneurysmal subarachnoid hemorrhage is considered **experimental, investigational or unproven.** The benefit for Medicare and Medicaid products will be in accordance to CMS mandated coverage as outlined in the current version of National Coverage Determination~~

MP261 Aqueous Drainage Shunt – Revised – Add Indication

INDICATIONS:
FDA-approved ab externo or ab interno aqueous drainage/shunt implants are considered to be medically necessary for the treatment of refractory primary open-angle glaucoma when first and second - line pharmacologic therapies such as, but not limited to latanoprost, timolol, brimonidine or dorzolamide have failed to control intra-ocular pressure. Aqueous drainage/shunt implants may be utilized as an alternative to laser trabeculectomy or as an alternative to a failed previous trabeculectomy.

The use of FDA-approved ab interno stents in conjunction with cataract surgery is considered to be medically necessary in members diagnosed with mild to moderate open angle glaucoma being treated with ocular hypotensive medication.

The use of one or two FDA-approved ab interno stents in conjunction with cataract surgery is considered to be medically necessary in individuals with mild-to-moderate open-angle glaucoma treated with ocular hypotensive medication.

MP270 Ocular Photoscreening – Revised – Add Exclusion

EXCLUSIONS:
The Plan does **NOT** provide coverage for ocular photoscreening for applications other than those listed under Indications because all other uses are considered **unproven** and **NOT COVERED.** There is insufficient evidence in the peer-reviewed published medical literature to establish the effectiveness of this treatment on health outcomes when compared to established treatments or technologies.

The Plan does NOT provide coverage for retinal birefringence scanning to detect eye misalignment or strabismus because it is considered **unproven** and **NOT COVERED**. There is insufficient evidence in the peer-reviewed published medical literature to establish the effectiveness of this treatment on health outcomes when compared to established treatments or technologies.

MP287 Shift Care – Revised – Revise Home Health Aide Criteria

Home Health Aide in Home or Outside of Home

In accordance with PA Code § 1249.54, home health aide service is considered medically necessary when ~~ALL of~~ the following criteria are met:

- The home health aide service is provided in conjunction with skilled care or, when personal care services are medically necessary; and
    - There is documentation of communication between the home health aide and a supervisory nurse regarding the member during recertification (60 days); and
- The assignment of home health aide services is made in accordance with a written treatment plan established by the member's attending physician or physician extender which indicates a need for personal care services, and the specific services to be furnished by the home health aide is determined by a registered nurse. If skilled care is not required, the members attending physician must certify that the personal care services are medically necessary.
- A registered nurse shall make a supervisory visit to the member's residence as needed in addition to the required every 60 day assessment ~~at least every 2 weeks~~, either when the home health aide is present to observe and assist, or when the home health aide is absent, to assess relationships and determine whether goals are being met. This includes ensuring approved home health aide to member ratios are adhered to, and that home health aides are sufficiently free from distractions or other responsibilities to competently perform their duties.

MP321 Gene Expression Profiling for Cutaneous Melanoma – Revised – Clarify PLA Criteria

COMMERCIAL AND MEDICARE BUSINESS SEGMENT:
Pigmented Lesion Assay (0089U)
Gene expression profiling for cutaneous melanoma utilizing the Pigmented Lesion Assay RNA gene expression test on skin samples obtained via adhesive patches (also called "tape stripping") is considered medically necessary when the following criteria are met:

- The lesion must meet one or more ABCDE criteria (Asymmetry, Border, Color, Diameter, Evolving)*
- Primary melanocytic skin lesions is between 5mm and 19mm
- Lesion skin is intact (i.e. non-ulcerated or non-bleeding lesions)
- Lesion does not contain a scar or has been previously biopsied
- Lesion is not located in areas of psoriasis, eczema or similar skin conditions
- Lesion has not already been diagnosed as melanoma or for which the clinical suspicion is sufficiently high that the treating clinician believes melanoma is a more likely diagnosis than not
- Lesion is **NOT** located on the ~~in areas other than~~ palms of hands, soles of feet, nails, mucous membranes and hair covered areas that cannot be trimmed.

*ABCDE criteria:
Asymmetry - The shape of one half does not match the other half.
Border that is irregular - The edges are often ragged, notched, or blurred in outline. The pigment may spread into the surrounding skin.
Color that is uneven - Shades of black, brown, and tan may be present. Areas of white, gray, red, pink, or blue may also be seen.
Diameter - There is a change in size, usually an increase. Melanomas can be tiny, but most are larger than 6 millimeters wide (about 1/4 inch wide).
Evolving - The mole has changed over the past few weeks or months.

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.

EXCLUSIONS:
The Plan currently considers the use of molecular profiling tests not specifically outlined in this policy to be **unproven** and **NOT COVERED.** At this time, published, peer-reviewed, medical literature to support the use of these tests or any other testing not specifically outlined in this policy is limited and insufficient to establish their analytical validity or clinical utility.

The following policies have been reviewed with no change to the policy section. Additional references or background information was added to support the current policy.

MP015 Experimental/Investigational
MP017 Ambulance Transport
MP038 Oral Health
MP065 Obesity Surgery
MP080 Cardiac Rehab
MP083 Contact Lenses
MP157 Prothrombin Time Home Testing
MP162 Salivary Hormone Testing For Menopause and Aging
MP177 Sensory Integration Therapy

MP194 Rhinophototherapy
MP260 Canaloplasty and Viscocanalostomy
MP296 Occipital Nerve Block
MP297 Suprascapular Nerve Block
MP300 Digital Breast Tomosynthesis
MP331 Inpatient Rehabilitation
MP332 Skilled Nursing Facility
MP341 TissueCypher Barrett's Esophagus Assay
MP362 Non-Invasive Home Ventilator
MP377 Therapeutic Apheresis
MP164 Light-based Treatment for Acne

Prior Authorization List

The Prior Authorization list has been revised. Providers are encouraged to refer to the following link:

https://www.geisinger.org/-/media/OneGeisinger/Files/PDFs/Provider/PriorAuthList.pdf?la=en

Sections with revisions are highlighted and updated monthly.