

Medicare Medical Policy

Skin and Tissue Substitutes

MEDICARE MEDICAL POLICY NUMBER: 371

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INSTRUCTIONS FOR USE: Company Medicare Medical Policies serve as guidance for the administration of plan benefits and do not constitute medical advice nor a guarantee of coverage. Company Medicare Medical Policies are reviewed annually to guide the coverage or non-coverage decision-making process for services or procedures in accordance with member benefit contracts (otherwise known as Evidence of Coverage or EOCs) and Centers of Medicare and Medicaid Services (CMS) policies, manuals, and other CMS rules and regulations. In the absence of a CMS coverage determination or specific regulation for a requested service, item or procedure, Company policy criteria or applicable utilization management vendor criteria may be applied. These are based upon published, peer-reviewed scientific evidence and evidence-based clinical practice guidelines that are available as of the last policy update. Coverage decisions are made on the basis of individualized determinations of medical necessity and the experimental or investigational character of the treatment in the individual case. In cases where medical necessity is not established by policy for specific treatment modalities, evidence not previously considered regarding the efficacy of the modality that is presented shall be given consideration to determine if the policy represents current standards of care.

The Company reserves the right to determine the application of Medicare Medical Policies and make revisions to these policies at any time. Any conflict or variance between the EOC and Company Medical Policy will be resolved in favor of the EOC.

SCOPE: Providence Health Plan, Providence Health Assurance, Providence Plan Partners, and Ayin Health Solutions as applicable (referred to individually as “Company” and collectively as “Companies”).

PRODUCT AND BENEFIT APPLICATION

Medicare Only

MEDICARE COVERAGE CRITERIA

IMPORTANT NOTE: More than one Centers for Medicare and Medicaid Services (CMS) reference may apply to the same health care service, such as when more than one coverage policy is available (e.g., both an NCD and LCD exist). All references listed should be considered for coverage decision-making. The Company uses the most current version of a Medicare reference available at the time of publication; however, these websites are not maintained by the Company, so Medicare references and their corresponding hyperlinks may change at any time. If there is a conflict between the Company Medicare Medical Policy and CMS guidance, the CMS guidance will govern.

Service	Medicare Guidelines
<i>Porcine Skin and Gradient Pressure Dressings</i>	NCD for Porcine Skin and Gradient Pressure Dressings (270.5)
<i>All Other Skin and/or Tissue Substitute Products Not Otherwise Addressed</i>	Company medical policy for Skin and Tissue Substitutes I. These services may be considered medically necessary for Medicare when the Company medical policy criteria are met. II. These services are considered not medically necessary for Medicare Plan members either when the Company medical policy criteria are not met <u>or</u> when a service is deemed “investigational” by the Company policy. <u>Services deemed “investigational” are considered not medically necessary for Medicare Plan members. See Policy Guidelines below.</u>

IMPORTANT NOTICE: While some services or items may appear medically indicated for an individual, they may also be a direct exclusion of Medicare or the member’s benefit plan. Such excluded services or items by Medicare and member EOCs include, but are not limited to, services or procedures considered to be cosmetic, not medical in nature, or those considered not medically reasonable or necessary under *Title XVIII of the Social Security Act, §1862(a)(1)(A)*. If there is uncertainty regarding coverage of a service or item, please review the member EOC or submit a pre-service organization determination request. Note that the Medicare Advance Beneficiary Notice of Noncoverage (ABN) form **cannot** be used for Medicare Advantage members. (*Medicare Advance Written Notices of Non-coverage. MLN006266 May 2021*)

POLICY CROSS REFERENCES

- [Cosmetic and Reconstructive Surgery](#), MP232
- [Breast Surgery: Reduction Mammoplasty, Reconstructive Surgery, and Implant Management](#), MP523

The full Company portfolio of Medicare Medical Policies is available online and can be [accessed here](#).

POLICY GUIDELINES

DOCUMENTATION REQUIREMENTS

Medical records documentation must clearly support the medical necessity of bioengineered skin and tissue substitutes. This would include the following:

- Characteristics of the wound/ulcer
- Wound/ulcer measurement
- Evidence of prior ineffective standard care, including the duration of this treatment
- The presence of qualifying or disqualifying conditions (i.e., HbA1C levels, ankle-brachial index [ABI])

MEDICARE AND MEDICAL NECESSITY

The Company policy for *PHA Medicare Medical Policy Development and Application* (MP50) provides details regarding Medicare's definition of medical necessity and the hierarchy of Medicare references and resources during the development of medical policies, as well as the Plan's use of evidence-based processes for policy development. In the absence of Medicare coverage policies (e.g., manual, national coverage determination [NCD], local coverage determination [LCD], article [LCA], etc.) which addresses the medical necessity of a given medical service, Medicare regulatory guidelines do allow Medicare Advantage Organizations (MAOs) to make their own coverage determinations, as long as the MAO applies an objective, evidence-based process, based on authoritative evidence. (*Medicare Managed Care Manual, Ch. 4, §90.5*)

The local Medicare Administrative Contractor (MAC) – Noridian – used to have a local coverage article (LCA) for *Use of Amniotic Membrane Derived Skin Substitutes* (A56156); however, Noridian retired this LCA on September 30, 2021. In addition, the Noridian LCD for *Wound and Ulcer Care* specifically states it does not apply to skin substitutes used in wound care. Therefore, for any service not addressed by a Medicare policy or guideline, the Company policy criteria will be applied.

Following an evidence-based assessment of current peer-reviewed medical literature, the Company may consider certain medical services or technologies to be “investigational.” The term “investigational” is not limited to devices or technologies which have not received the appropriate governmental regulatory approval (e.g., U.S. Food and Drug Administration [FDA]), but rather may also mean the procedure, device, or technology does not meet all of the Company's technology assessment criteria, as detailed within the Company policy for *Definition: Experimental/Investigational* (MP5).

Only medically reasonable and necessary services or items which treat illness or injury are eligible for Medicare coverage, as outlined in *Title XVIII of the Social Security Act, §1862(a)(1)(A)*. Thus, services which lack scientific evidence regarding safety and efficacy because they are investigational are “not medically reasonable or necessary” for Medicare Plan members. (*Medicare Claims Processing Manual, Ch. 23, §30 A*)

REGULATORY STATUS

U.S. FOOD & DRUG ADMINISTRATION (FDA)

While clearance by the Food and Drug Administration (FDA) is a prerequisite for Medicare coverage, the 510(k) premarket clearance process does not in itself establish medical necessity. Medicare payment policy is determined by the interaction of numerous requirements, including but not limited to, the availability of a Medicare benefit category and other statutory requirements, coding and pricing guidelines, as well as national and local coverage determinations and clinical evidence.

BILLING GUIDELINES AND CODING

GENERAL

Codes billed in association with the primary product code may also be denied if the product is not covered per the policy criteria above.

The following products are considered medically necessary and covered when billed for vocal cord paralysis treatment:

Products

- Q4112 (Cymetra)
- Q4114 (Integra flowable wound matrix)

Diagnosis codes

- J38.02 Paralysis of vocal cords and larynx, bilateral
- J38.00 Paralysis of vocal cords and larynx, unspecified
- J38.01 Paralysis of vocal cords and larynx, unilateral

CODES*		
Note:		
<ul style="list-style-type: none"> • Some codes which require prior authorization may have these requirements waived for select diagnosis codes (F64.0, F64.1, F64.8, or F64.9). • Please refer to the Company non-covered and prior authorization lists for additional information. 		
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	Application of skin substitute graft to trunk, arms, legs, total wound surface area up to 100 sq cm; each additional 25 sq cm wound surface area, or part thereof (List separately in addition to code for primary procedure)
	15273	Application of skin substitute graft to trunk, arms, legs, total wound surface area greater than or equal to 100 sq cm; first 100 sq cm wound surface area, or 1% of body area of infants and children
	15274	Application of skin substitute graft to trunk, arms, legs, total wound surface area greater than or equal to 100 sq cm; each additional 100 sq cm wound surface area, or part thereof, or each additional 1% of body area of infants and children, or part thereof (List separately in addition to code for primary procedure)

	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	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; each additional 25 sq cm wound surface area, or part thereof (List separately in addition to code for primary procedure)
	15277	Application of skin substitute graft to face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits, total wound surface area greater than or equal to 100 sq cm; first 100 sq cm wound surface area, or 1% of body area of infants and children
	15278	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; each additional 100 sq cm wound surface area, or part thereof, or each additional 1% of body area of infants and children, or part thereof (List separately in addition to code for primary procedure)
	15777	Implantation of biologic implant (eg, acellular dermal matrix) for soft tissue reinforcement (ie, breast, trunk) (List separately in addition to code for primary procedure)
HCPCS	A2001	Innovamatrix ac, per square centimeter
	A2002	Mirragen advanced 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
	A2011	Supra sdrm, per square centimeter
	A2012	Suprathel, per square centimeter
	A2013	Innovamatrix fs, per square centimeter
	A2014	Omeza collagen matrix, per 100 mg
	A2015	Phoenix wound matrix, per square centimeter
	A2016	Permeaderm b, per square centimeter
	A2017	Permeaderm glove, each
	A2018	Permeaderm c, per square centimeter
	A4100	Skin substitute, FDA cleared as a device, not otherwise specified
	C1763	Connective tissue, non-human (includes synthetic)
	C1781	Mesh (implantable)
	C1832	Autograft suspension, including cell processing and application, and all system components
	C9356	Tendon, porous matrix of cross-linked collagen and glycosaminoglycan matrix (tenoglide tendon protector sheet), per square centimeter
	C9363	Skin substitute, integra meshed bilayer wound matrix, per square centimeter
	C9364	Porcine implant, permacol, per square centimeter
	C9399	Unclassified drugs or biologicals
	Q4100	Skin substitute, not otherwise specified
	Q4101	Apligraf, per square centimeter
	Q4102	Oasis wound matrix, per square centimeter

Q4103	Oasis burn matrix, per square centimeter
Q4104	Integra bilayer matrix wound dressing (bmwd), per square centimeter
Q4105	Integra dermal regeneration template (drt) or integra omnigraft dermal regeneration matrix, 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
Q4116	Alloderm, per square centimeter
Q4115	Alloskin, per square centimeter
Q4117	Hyalomatrix, per square centimeter
Q4118	Acell 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, tranzgraft or integuply, per square centimeter
Q4127	Talymed, per square centimeter
Q4128	Flex hd, or allopatch hd, per square centimeter
Q4130	Strattice tm, per square centimeter
Q4132	Grafix core, per square centimeter
Q4133	Grafix prime , grafixpl prime, stravix and stravixpl, 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, architect px, or architect fx, 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 and plurivest, per square centimeter
Q4154	Biovance, per square centimeter
Q4155	Neoxflo or clarixflo, 1 mg
Q4156	Neox 100 or clarix 100, per square centimeter

Q4157	Revitalon, per square centimeter
Q4158	Kerecis omega3, per square centimeter
Q4159	Affinity, per square centimeter
Q4160	Nushield, per square centimeter
Q4161	Bio-connekt wound matrix, per square centimeter
Q4162	Woundex flow, bioskin flow, 0.5 cc
Q4163	Woundex, bioskin, per square centimeter
Q4164	Helicoll, per square centimeter
Q4165	Keramatrix, per square centimeter
Q4166	Acell 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
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
Q4183	Surgigraft, per square centimeter
Q4184	Cellesta, per square centimeter
Q4185	Cellesta flowable amnion (25 mg per cc); per 0.5 cc
Q4186	Epifix, per square centimeter
Q4187	Epicord, per square centimeter
Q4188	Amnioarmor, per square centimeter
Q4189	Artacent ac, 1 mg
Q4190	Artacent ac, per square centimeter
Q4191	Restorigin, per square centimeter
Q4192	Restorigin, 1 cc
Q4193	Coll-e-derm, per square centimeter
Q4194	Novachor, per square centimeter
Q4195	Puraply, per square centimeter
Q4196	Puraply am, per square centimeter
Q4197	Puraply xt, per square centimeter
Q4198	Genesis amniotic membrane, per square centimeter
Q4199	Cygnus matrix, per square centimeter
Q4200	Skin te, per square centimeter
Q4201	Matrion, per square centimeter
Q4202	Keroxx (2.5g/cc), 1cc
Q4203	Derma-gide, per square centimeter
Q4204	Xwrap, per square centimeter
Q4205	Membrane graft or membrane wrap, per square centimeter
Q4206	Fluid flow or fluid GF, 1 cc

Q4208	Novafix, per square centimeter
Q4209	Surgraft, per square centimeter
Q4210	Axolotl graft or axolotl dualgraft, per square centimeter
Q4211	Amnion bio or Axobiomembrane, per square centimeter
Q4212	Allogen, per cc
Q4213	Ascent, 0.5 mg
Q4214	Cellesta cord, per square centimeter
Q4215	Axolotl ambient or axolotl cryo, 0.1 mg
Q4216	Artacent cord, per square centimeter
Q4217	Woundfix, BioWound, Woundfix Plus, BioWound Plus, Woundfix Xplus or BioWound Xplus, per square centimeter
Q4218	Surgicord, per square centimeter
Q4219	Surgigraft-dual, per square centimeter
Q4220	BellaCell HD or Surederm, per square centimeter
Q4221	Amniowrap2, per square centimeter
Q4222	Progenamatrix, per square centimeter
Q4224	Human health factor 10 amniotic patch (hhf10-p), per square centimeter
Q4225	Amniobind, per square centimeter
Q4226	MyOwn skin, includes harvesting and preparation procedures, per square centimeter
Q4227	Amniocore, per square centimeter
Q4229	Cogenex amniotic membrane, per square centimeter
Q4230	Cogenex flowable amnion, per 0.5 cc
Q4231	Corplex p, per cc
Q4232	Corplex, per square centimeter
Q4233	Surfactor or nudyn, per 0.5 cc
Q4234	Xcellerate, per square centimeter
Q4235	Amniorepair or altiPLY, per square centimeter
Q4236	Carepatch, per square centimeter
Q4237	Cryo-cord, per square centimeter
Q4238	Derm-maxx, per square centimeter
Q4239	Amnio-maxx or amnio-maxx lite, per square centimeter
Q4240	Corecyte, for topical use only, per 0.5 cc
Q4241	Polycyte, for topical use only, per 0.5 cc
Q4242	Amniocyte plus, per 0.5 cc
Q4244	Procenta, per 200 mg
Q4245	Amniotext, per cc
Q4246	Coretext or protext, per cc
Q4247	Amniotext patch, per square centimeter
Q4248	Dermacyte amniotic membrane allograft, per square centimeter
Q4249	AmniPLY, for topical use only, per square centimeter
Q4250	Amnioamp-mp, per square centimeter
Q4251	Vim, per square centimeter
Q4252	Vendaje, per square centimeter
Q4253	Zenith amniotic membrane, per square centimeter
Q4254	Novafix dl, per square centimeter
Q4255	Reguard, for topical use only, per square centimeter
Q4256	Mlg-complete, per square centimeter
Q4257	Relese, per square centimeter

Q4258	Enverse, per square centimeter
Q4259	Celera dual layer or celera dual membrane, per square centimeter
Q4260	Signature apatch, per square centimeter
Q4261	Tag, per square centimeter
Q4262	Dual layer impax membrane, per square centimeter
Q4263	Surgraft tl, per square centimeter
Q4264	Cocoon membrane, per square centimeter

***Coding Notes:**

- The code list above is provided as a courtesy and may not be all-inclusive. Inclusion or omission of a code from this policy neither implies nor guarantees reimbursement or coverage. Some codes may not require routine review for medical necessity, but they are subject to provider contracts, as well as member benefits, eligibility and potential utilization audit. According to Medicare, “presence of a payment amount in the MPFS and the Medicare physician fee schedule database (MPFSDB) does not imply that CMS has determined that the service may be covered by Medicare.” The issuance of a CPT or HCPCS code or the provision of a payment or fee amount by Medicare does **not** make a procedure medically reasonable or necessary or a covered benefit by Medicare. (*Medicare Claims Processing Manual, Chapter 23 - Fee Schedule Administration and Coding Requirements, §30 - Services Paid Under the Medicare Physician’s Fee Schedule, A. Physician’s Services*)
- All unlisted codes are reviewed for medical necessity, correct coding, and pricing at the claim level. If an unlisted code is submitted for non-covered services addressed in this policy then it will be **denied as not covered**. If an unlisted code is submitted for potentially covered services addressed in this policy, to avoid post-service denial, **prior authorization is recommended**.
- See the non-covered and prior authorization lists on the Company [Medical Policy, Reimbursement Policy, Pharmacy Policy and Provider Information website](#) for additional information.
- HCPCS/CPT code(s) may be subject to National Correct Coding Initiative (NCCI) procedure-to-procedure (PTP) bundling edits and daily maximum edits known as “medically unlikely edits” (MUEs) published by the Centers for Medicare and Medicaid Services (CMS). This policy does not take precedence over NCCI edits or MUEs. Please refer to the CMS website for coding guidelines and applicable code combinations.

REFERENCES

None

POLICY REVISION HISTORY

DATE	REVISION SUMMARY
3/2023	New Medicare Advantage medical policy