

Medicare Medical Policy

Skin and Tissue Substitutes

MEDICARE MEDICAL POLICY NUMBER: 371

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| Effective Date: 2/1/2024 | MEDICARE COVERAGE CRITERIA | 2 |
| Last Review Date: 1/2024 | POLICY CROSS REFERENCES..... | 2 |
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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, and Providence Plan Partners 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 when the Company medical policy criteria are not met. <u>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

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)*.

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.

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.

During the MAO review, an evidence-based process must be used. This includes using authoritative evidence, such as studies performed by government agencies (i.e., the FDA), well-designed clinical studies that appeared in peer reviewed journals, and evaluations performed by independent technology assessment groups. (*Medicare Managed Care Manual, Ch. 4, §90.5*)

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) |

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| | 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 |
| | A2019 | Kerecis omega3 marigen shield, per square centimeter |
| | A2020 | Ac5 advanced wound system (ac5) |
| | A2021 | Neomatrix, per square centimeter |
| | A2022 | Innovaburn or innovamatrix xl, per square centimeter |
| | A2023 | Innovamatrix pd, 1 mg |
| | A2024 | Resolve matrix, per square centimeter |
| | A2025 | Miro3d, per cubic 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 |

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| 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 |

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| Q4155 | Neoxflo or clariflo, 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 |

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| 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 or dermabind tl, 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 |

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| 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 |
| Q4265 | Neostim tl, per square centimeter |
| Q4266 | Neostim membrane, per square centimeter |
| Q4267 | Neostim dl, per square centimeter |
| Q4268 | Surgraft ft, per square centimeter |
| Q4269 | Surgraft xt, per square centimeter |
| Q4270 | Complete sl, per square centimeter |
| Q4271 | Complete ft, per square centimeter |
| Q4272 | Esano a, per square centimeter |
| Q4273 | Esano aaa, per square centimeter |
| Q4274 | Esano ac, per square centimeter |
| Q4275 | Esano aca, per square centimeter |
| Q4276 | Orion, per square centimeter |
| Q4277 | Woundplus membrane or e-graft, per square centimeter |
| Q4278 | Epieffect, per square centimeter |
| Q4280 | Xcell amnio matrix, per square centimeter |
| Q4281 | Barrera SL or barrera DL, per square centimeter |
| Q4282 | Cygnus Dual, per square centimeter |
| Q4283 | Biovance tri-layer or biovance 3l, per square centimeter |
| Q4284 | Dermabind sl, per square centimeter |
| Q4285 | Nudyn dl or Nudyn dl mesh, per square centimeter |
| Q4286 | Nudyn sl or Nudyn slw, per square centimeter |
| Q4279 | Vendaje ac, per square centimeter |
| Q4287 | Dermabind dl, per square centimeter |
| Q4288 | Dermabind ch, per square centimeter |
| Q4289 | Revoshield + amniotic barrier, per square centimeter |
| Q4290 | Membrane wrap-hydro, per square centimeter |
| Q4291 | Lamellas xt, per square centimeter |
| Q4292 | Lamellas, per square centimeter |
| Q4293 | Acesso dl, per square centimeter" |
| Q4294 | Amnio quad-core, per square centimeter |
| Q4295 | Amnio tri-core amniotic, per square centimeter |
| Q4296 | Rebound matrix, per square centimeter |
| Q4297 | Emerge matrix, per square centimeter |
| Q4298 | Amniocore pro, per square centimeter |
| Q4299 | Amnicore pro+, per square centimeter |
| Q4300 | Acesso tl, per square centimeter |
| Q4301 | Activate matrix, per square centimeter |

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| | Q4302 | Complete aca, per square centimeter |
| | Q4303 | Complete aa, per square centimeter |
| | Q4304 | Grafix plus, 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 |
| 4/2023 | Q2 2023 code update |
| 7/2023 | Q3 2023 code update |
| 10/2023 | Q4 2023 code update |
| 1/2024 | Q1 2024 code update |
| 2/2024 | Annual review, no change to criteria |