



## Medica Central Coverage Policy

**Policy Name:** Skin and Soft Tissue-Engineered Substitutes for Wound and Surgical Care MP9655

**Effective Date:** 03/01/2025

### Important Information – Please Read Before Using This Policy

These services may or may not be covered by all Medica Central plans. Coverage is subject to requirements in applicable federal or state laws. Please refer to the member's plan document for other specific coverage information. If there is a difference between this general information and the member's plan document, the member's plan document will be used to determine coverage. With respect to Medicare, Medicaid, and other government programs, this policy will apply unless these programs require different coverage.

Members may contact Medica Customer Service at the phone number listed on their member identification card to discuss their benefits more specifically. Providers with questions may call the Provider Service Center. Please use the Quick Reference Guide on the Provider Communications page for the appropriate phone number. <https://mo-central.medica.com/Providers/SSM-employee-health-plan-for-IL-MO-OK-providers>

Medica Central coverage policies are not medical advice. Members should consult with appropriate health care providers to obtain needed medical advice, care, and treatment.

### Coverage Policy

Postmastectomy breast reconstructive surgery is **COVERED** when using any of the following tissue-engineered skin substitutes:

- AlloDerm®
- AlloMax™
- AlloMend®
- Cortiva®
- DermACELL™
- DermaMatrix™
- FlexHD®
- Graftjacket®
- hMatrix®
- Neoform™
- Strattice®

Treatment of (1) non-infected wounds, or (2) non-infected chronic ulcers (diabetic or venous insufficiency) of the lower-extremity, either of which have not adequately responded to conventional therapy, is **COVERED** when using any of the following tissue-engineered skin substitutes:

- AlloPatch HD® Acellular Dermis

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- AmnioBand® (Guradian)
- Apligraf®
- Dermagraft®
- DermACELL AWM®
- EpiFix®
- EpiCord™
- Grafix® Core.
- Grafix® Prime.
- Graftjacket® Regenerative Tissue Matrix
- Integra®: Omnigraft Dermal Regeneration Matrix (also known as Omnigraft), Dermal Regeneration Template, Wound Matrix, Primatrix and Bilayer Matrix Wound Dressing (excludes flowable wound matrix)
- Oasis® Wound Matrix
- TheraSkin®

Treatment of deep dermal or full thickness burns (2<sup>nd</sup> or 3<sup>rd</sup> degree burns) is **COVERED** when using any of the following tissue-engineered skin substitutes:

- Epicel® (humanitarian device exemption [HDE])
- Integra® Dermal Regeneration Template™
- OrCel™ (HDE)
- TransCyte®
- Biobrane®

Treatment of Stevens-Johnson syndrome and toxic epidermal necrolysis is **COVERED** when using:

- Biobrane®

Treatment of dystrophic epidermolysis bullosa is **COVERED** when using:

- Dermagraft® (HDE)
- OrCel™ (HDE)

All other uses of the tissue-engineered skin substitutes not listed above are investigative and unproven and therefore **NOT COVERED**. There is insufficient reliable evidence in the form of high quality peer-reviewed medical literature to establish the efficacy or effects on health care outcomes.

All other tissue-engineered skin substitutes not listed above are investigative and therefore **NOT COVERED** for all indications (see Appendix). There is insufficient reliable evidence in the form of high quality peer-reviewed medical literature to establish the efficacy or effects on health care outcomes.

**Note:** The FDA has granted a humanitarian device exemption (HDE) for certain tissue-engineered skin substitutes (e.g., Dermagraft®, OrCel™, and Epicel®). Medica considers an FDA-approved HDE device medically necessary when all of the FDA-required criteria are met. For a current list of HDE-approved devices, refer to the FDA HDE Database at: <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfHDE/hde.cfm>

## Medica Central Coverage Policy

### Description

Tissue-engineered skin substitutes are used to provide temporary wound coverage, assist in wound closure, reduce healing time, minimize post-operative contractures, and improve functional abilities and overall quality of life.

Tissue-engineered skin substitutes may be cellular or acellular, biological or biosynthetic. Cellular products contain living cells such as fibroblasts and keratinocytes within a matrix, and may be allogenic, obtained from another individual, or autogenic, from the same individual. Some products are derived from other species (e.g., bovine, porcine) and are referred to as xenografts. Acellular (i.e., cadaveric human dermis with cellular material removed) products contain a matrix or scaffold composed of materials such as collagen, hyaluronic acid, and fibronectin.

Biological products contain no synthetic components. Examples of acellular products are: Alloderm, Epicel, Graftjacket, Oasis, and PriMatrix. Biosynthetic products contain both biological and synthetic components, such as silicone. Examples include Biobrane, Apligraf, Dermagraft, and Integra. Manufacturing processes of tissue-engineered skin substitutes products vary by company in a number of ways including additives (e.g., antibiotics, surfactants, proteins and growth factors), hydration (wet, freeze dried) and required preparation (e.g., multiple rinses, rehydration).

Skin substitutes have been proposed for a variety of conditions and procedures including breast reconstruction, ocular defects, plantar fasciitis, hernia repair, chronic wounds, surgical wounds and treatment of severe burns.

### FDA Approval

Products regulated as human tissue are regulated by the American Association of Tissue Banks (AATB) and are therefore not subject to FDA approval. These products include, but are not limited to, Arthroflex, AlloDerm®, and Graftjacket.

Other products are primarily used to protect wounds and provide scaffolding for healing. These products are approved by the FDA 510(k) process and include (but are not limited to) Oasis® Wound Matrix (Cook Biotech), and Primatrix™ (TEI Biosciences).

Products classified by the FDA as interactive wound and burn dressings are approved under the PMA process as class III, high risk devices and include, but are not limited to, Dermagraft® (Advanced Tissue Sciences), Apligraf® (Organogenesis Inc.), and OrCel™ (Bilayered Cellular Matrix).

### Prior Authorization

Prior authorization is not required. However, services with specific coverage criteria may be reviewed retrospectively to determine if criteria are being met. Retrospective denial may result if criteria are not met.

### Coding Considerations

Use the current applicable CPT/HCPCS code(s).



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|                          | Committee/Source                                  | Date(s)           |
|--------------------------|---|-------------------|
| <b>Document Created:</b> | Medical Policy Committee/Health Services Division | May 17, 2023      |
| <b>Revised:</b>          | Medical Policy Committee/Health Services Division | December 20, 2023 |
| <b>Reviewed:</b>         | Medical Policy Committee/Health Services Division | December 20, 2023 |

Original Effective Date: 09/01/2023

Re-Review Date(s):

Administrative Update: 02/20/2025

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## Medica Central Coverage Policy

### Appendix 1

The following table provides a list of tissue-engineered skin substitute products that The Health Plan considers experimental and investigational, and therefore not medically necessary for **ALL** indications. (Note: this list may not be all-inclusive)

| <b>Codes</b>                     | <b>Product name</b>  | <b>Reason(s) for Request (this list may not be all inclusive)</b>  |
|----------------------------------|--|--|
| A2020                            | AC5 Advanced Wound System (AC5)  | Wound care   |
| Q4325                            | ACApatch   | Protective wound covering and barrier for acute and chronic wounds |
| Q4118<br>Q4119<br>Q4166          | ACell® MatriStem®Wound Sheets [also called urinary bladder matrix (UBM), Cytal, MicroMatrix];<br>Acell® Powder Wound Dressing;<br>Acell® Ubm Hydrated Wound Dressing;<br>Acell® Ubm Lyophilized Wound Dressing | Wound care   |
| Q4293<br>Q4300<br>Q4311<br>Q4312 | Acesso DL<br>Acesso TL<br>Acesso SL<br>Acesso AC   | Protective wound covering and barrier in acute and chronic wounds  |
| Q4100<br>C9399                   | Actigraft®   | Wound care   |
| Q4100<br>C9399                   | Actishield™  | Soft and/or hard tissue repair                                     |
| Q4100,<br>C9399                  | ActiveBarrier®   | Wound care   |
| Q4100                            | ActiveMatrix®  | Connective tissue repair   |
| Q4159                            | Affinity®  | Wound care   |
| Q4212                            | AlloGen™   | Liquid allograft designed to cushion the joint capsule             |
| Q4323                            | alloPLY  | Protective wound covering and barrier for acute and chronic wounds |
| Q4141                            | Alloskin™ AC   | Wound care   |
| Q4123                            | AlloSkin™ RT   | Wound care   |
| Q4115                            | AlloSkin TM  | Wound care   |
| Q4150                            | Allowrap® DS or Dry  | Wound care   |
| Q4316                            | AmchoPlast   | Wound care   |
| Q4250                            | AmnioAMP-MP  | Wound care   |

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| <b>Codes</b>            | <b>Product name</b>  | <b>Reason(s) for Request (this list may not be all inclusive)</b> |
|-------------------------|--|---|
| Q4188                   | AmnioArmor   | Wound care  |
| Q4100<br>C9399          | AmnioCare®   | Wound care, tendon/nerve repair                                   |
| Q4100<br>J3590          | AmnioClear® (LTC and flowable)                             | Wound care, surgical barrier                                      |
| Q4227                   | AmnioCord®   | Wound care  |
| Q4298<br>Q4299          | AmniCore Pro<br>AmniCore Pro+                              | Wound care, surgical barrier                                      |
| J3590<br>Q4242          | Amniocyte™ Flowable Matrix;<br>AmnioCyte Plus Injectable   | Connective tissue repair  |
| Q4137                   | Amnioexcel® or BioDExCel®                                  | Wound care, soft tissue repair                                    |
|                         | AmnioFill® Human Placental Tissue Allograft                | Wound care, soft tissue repair                                    |
|                         | AmnioFlex™   | Wound care, soft tissue repair                                    |
| Q4100<br>C9399<br>J3590 | Amniofix® Amniotic Membrane;<br>Amniofix® Injectable       | Wound care, tendon / nerve repair                                 |
| Q4100<br>C9399          | AmnioHeal®   | Wound care  |
| Q4139                   | Amniomatrix or biodmatrix Suspension Allograft, injectable | Wound care, soft tissue repair                                    |
| Q4239                   | Amnio-Maxx or Amnio-Maxx Lite                              | Wound care, soft tissue repair                                    |
| Q4100<br>C9399          | AmnioMTM™ (Multipotential Tissue Matrix)                   | Wound care, soft tissue repair                                    |
| Q4211                   | Amnion bio or Axomembrane                                  | Wound care, soft tissue repair                                    |
| Q4100<br>C9399          | AmnioPro Membrane™;<br>AmnioPro Flow;<br>Amniogen-c™       | Wound care, soft tissue repair                                    |
| Q4294<br>Q4295          | Amnio Quad-Core<br>Amnio Tri-Core Amniotic                 | Wound care, surgical barrier                                      |
| Q4235                   | Amniorepair/Altiplay                                       | Wound care  |
| Q4100<br>C9399          | Amnios®/Amnios® RT   | Wound care  |
| Q4100                   | AmnioShield®   | Wound care  |

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| <b>Codes</b>   | <b>Product name</b>  | <b>Reason(s) for Request (this list may not be all inclusive)</b>  |
|----------------|--|--|
| Q4100<br>C9399 | Amniovo®   | Soft tissue repair, tendon repair                                  |
| Q4225          | AmnioBind  | Wound care   |
| Q4181          | Amnio Wound®   | Wound care   |
| Q4100<br>C9399 | Amniostrip™  | Wound care, soft tissue repair                                     |
| Q4245<br>Q4247 | Amniotext® (injectable suspension or patch)                                    | Tissue defect  |
| Q4324          | AmnioTX  | Protective wound covering and barrier for acute and chronic wounds |
| Q4148          | Amniox®  | Tissue repair, carpal tunnel repair                                |
|                | Aongen™ Collagen Matrix  | Wound care   |
| Q4221          | AmnioWrap2™  | Wound care   |
| Q4249          | Amniply®   | Wound care   |
| Q4147          | Architect™ ECM (Stabilized Collagen Matrix);<br>Architect PX;<br>Architect™ FX | Wound care   |
| Q4333          | ArdeoGraft (Dual layer human chorionic membrane)                               | Wound care   |
| Q4169          | Artacent® Flex   | Surgical barrier   |
| Q4169<br>Q4216 | Artacent® Wound,<br>Artacent Cord  | Surgical barrier   |
| Q4190<br>Q4169 | Artacent® AC Membrane;<br>Artacent® Powder                                     | Surgical barrier   |
|                | Artelon® Dynamic Matrix  | Scaffold for tissue ingrowth, ligament / tendon reconstruction     |
| Q4189          | Artacent ac (flowable)   | Wound care   |
| Q4100<br>C1762 | Arthrex® Amnion matrix   | Orthopedic barrier or wrap   |
| J3590          | Arthrex® Amnion viscous  | Orthopedic barrier or wrap   |
| C9250          | ARTISS®  | Wound care, burns  |
| Q4125          | ArthroFlex (flexGraft®)  | Soft-tissue repair and tendon augmentation/reconstruction          |
| Q4213          | Ascent® Cord   | Wound care, joint and tendon repair                                |

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| <b>Codes</b>                     | <b>Product name</b>   | <b>Reason(s) for Request (this list may not be all inclusive)</b>    |
|----------------------------------|---|--|
|                                  | Atlas® Wound Matrix   | Wound care, joint and tendon repair                                  |
| Q4100<br>C9399                   | Avance® Nerve Graft   | Peripheral nerve repair  |
| Q4211                            | AxoBioMembrane®   | Soft tissue repair   |
| Q4100                            | Axograft™   | Spinal arthrodesis procedures  |
| Q4100<br>C9399<br>C1763          | AxoGuard® (Nerve Protector, Nerve Connector, Nerve Cap)(AxoGen)   | Peripheral nerve repair  |
| Q4215<br>Q4210<br>Q4331<br>Q4332 | Axolotl Graft (Ambient, Cryo, DualGraft, Graft)   | Soft tissue repair   |
| Q4281                            | Barrera SL or Barrera DL  | Protective barrier in wound care                                     |
| Q4220                            | BellaCell HD or SureDerm  | Soft tissue repair   |
| Q4100<br>C9399                   | BellaDerm® Acellular Hydrated Dermis  | Integumental tissue repair, soft tissue repair                       |
| Q4161                            | Bio-Connekt Wound Matrix  | Wound care   |
| Q4138                            | BioDDryFlex® Resorbable amniotic membrane   | Adhesion barrier   |
| Q4100<br>C1781                   | Biodesign® (Surgisis®) AFP  | Breast reconstruction, anal and rectal fistula repair, hernia repair |
| Q4100<br>C1763                   | Biodesign® Dural Graft;<br>Biodesign® Duraplasty Graft;<br>Biodesign® ENT Repair Graft;<br>Biodesign® Otologic Repair Graft | Dura mater, sinonasal, tympanic membrane                             |
| Q4137                            | BioDExCel™ (also marketed under trade name AmnioExCel)  | Wounds care  |
| Q4199<br>C9399                   | BioDFactor™ Viable Tissue Matrix  | Wound care, soft tissue repair                                       |
| Q4100<br>C9399                   | BioDRestore™ Elemental Tissue Matrix  | Wound care, soft tissue repair                                       |
| Q4138                            | BioDfence® Dryflex  | Surgical wrap/barrier, tendon repair                                 |
| Q4140                            | BioDfence® Human Amniotic Allograft   | Surgical wrap/barrier, tendon repair                                 |
| Q4138                            | BioDFence® Placental Tissue Membrane  | Wound care   |



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| <b>Codes</b>                     | <b>Product name</b>  | <b>Reason(s) for Request (this list may not be all inclusive)</b>                                  |
|----------------------------------|--|--|
| Q4139                            | BioDmatrix or Amniomatrix  | Wound care   |
| Q4100<br>C9399                   | BioFix® Flow Placental Tissue Allograft;<br>BioFix® Plus                                       | Wound care   |
| Q4228                            | BioNextPatch   | Burn care, wound care  |
| Q4162<br>Q4163                   | BioSkin, BioSkin Flow  | Wound care   |
|                                  | Biostat Biologx  | Wound healing  |
|                                  | BIOTAPE XM® Tissue Matrix  | Reinforcement matrix for soft tissue augmentation and tendon repair surgery                        |
| Q4154<br>Q4283                   | BioVance®, Biovance Tri-Layer, or Biovance 3L  | Wound care   |
| Q4217                            | BioWound Membrane;<br>Plus Membrane;<br>XPlus Membrane   | Wound care   |
|                                  | Bridge Extracellular Collagen Matrix   | Wound care   |
| Q4322                            | CaregraFT  | Protective wound covering and barrier for acute and chronic wounds.                                |
| Q4100<br>C9399                   | CardioCel®   | Pericardial closure, cardiac or vascular defect repair, congenital heart deformities, heart valves |
|                                  | CardioGRAFT® (MatrACELL)   | Aortic reconstruction (stenosis/atresia), repair of right vent outflow tract                       |
| Q4236                            | carePATCH®   | Burn care, wound care  |
|                                  | Celaderm™  | Wound care   |
| Q4259                            | Celera Dual Layer or Celera Dual Membrane  | Wound care   |
|                                  |  |  |
| Q4184<br>Q4214<br>Q4185          | Cellesta™ Amniotic Membrane;<br>Cellesta™ Duo;<br>Cellesta™ Cord;<br>Cellesta™ Flowable Amnion | Wound care   |
| Q4156<br>Q4148<br>Q4100<br>C9399 | CLARIX® 100 Quick-Peel Regenerative Matrix;<br>CLARIX® CORD 1k;<br>CLARIX® Regenerative Matrix | Surgical covering, wrap or barrier   |

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| <b>Codes</b>   | <b>Product name</b>                                   | <b>Reason(s) for Request (this list may not be all inclusive)</b>                           |
|----------------|---|---|
| Q4155          | CLARIX™ FLO (injectable)                              | Surgical covering, wrap or barrier, integumental tissue repair                              |
| Q4264          | Cocoon membrane                                       | Wound care  |
| Q4193          | Coll-e-Derm™  | Breast reconstruction, abdominal wall repair, soft tissue augmentation, tendon augmentation |
| Q4229<br>Q4230 | Cogenex amniotic membrane;<br>Cogenex Flowable amnion | Burn care, wound care   |
| Q4100          | CollaFix™   | Scaffold for mechanical substitution or augmentation for tendon/ligament repair             |
| Q4303          | Complete AA   | Wound care  |
| Q4302          | Complete ACA  | Wound care  |
| Q4270<br>Q4271 | Complete SL<br>Complete FT                            | Wound care  |
| Q4100<br>C1781 | Conexa™ Reconstructive Tissue Matrix                  | Tendon repair   |
| Q4240          | Corecyte™   | Tissue repair   |
| Q4246          | CoreText or Protext                                   | Tissue repair   |
| Q4100<br>C9399 | Cormatrix CanGaroo™ Protect ECM Envelope              | Implantable electronic device pocket  |
| Q4100<br>C9399 | CorMatrix® ECM® for Cardiac Tissue Repair             | Intracardiac patch  |
| Q4100<br>C9399 | CorMatrix® ECM® for Carotid Repair                    | Carotid artery repair   |
| Q4100<br>C9399 | CorMatrix® ECM® for Pericardial Closure               | Pericardial repair  |
| Q4231<br>Q4232 | Corplex or Corplex P                                  | Wound care<br>Connective tissue repair  |
|                | C-QUR™ Biosynthetic Mesh                              | Abdominal surgical repair procedures (hernia repair)  |
| Q4100<br>C9399 | Creos™ Xenoprotect                                    | Bone and tissue regeneration  |
| Q4237          | Cryo-Cord   | Wound care  |

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| Codes                                     | Product name   | Reason(s) for Request (this list may not be all inclusive)  |
|---|--|---|
| Q4100<br>C9399                            | CryoMatrix®  | Connective tissue repair  |
| Q4100<br>C9399                            | CryoSkin® (old name)<br>Neveskin Classic (new name)  | Product intended for beautification, not a medical device.  |
|   | Cryotext™  | Wound care<br>Connective tissue repair  |
| Q4170<br>Q4199<br>Q4282                   | CYGNUS Matrix™;<br>CYGNUS Max™;<br>CYGNUS Solo™<br>CYGNUS Dual:  | Wound care, nerve wrap  |
| Q4166<br>Q4120<br><del>Q4170</del>        | Cytal® Wound Matrix (formerly MatriStem);<br>Cytal® Multilayer Matrix;<br>Cytal® Micro Matrix;<br>Cytal® Burn Matrix | Wound care  |
| Q4313<br>Q4288<br>Q4287<br>Q4284<br>Q4225 | DermaBind FM,<br>DermaBind™ CH,<br>DermaBind DL,<br>DermaBind SL,<br>DermaBind TL                                    | Repair, reconstruction and replacement of skin  |
| Q4100                                     | DermaClose® RC   | Tissue expander, skin anchors   |
| Q4248                                     | Dermacyte Amniotic Membrane Allograft®   | Wound care  |
| Q4203                                     | Derma-Gide®, Geistlich DermaGide®<br>Advanced Wound Matrix   | Wound care and soft tissue repair   |
| Q4152                                     | DermaPure™   | Wound care: diabetic foot ulcers, venous stasis ulcers, wounds refractory to more conservative care |
| Q4126                                     | DermaSpan™   | Wound covering, Tendon repair: Achilles, lateral ankle stabilization, anterior/posterior tibial     |
| Q4153                                     | Dermavest™ or Plurivest™   | Wound care  |
| Q4238                                     | Derm-Maxx  | Wound covering  |
| Q4138                                     | DryFlex, Biodfence   | Shoulder repair   |
| Q4262                                     | Dual Layer Impax Membrane  | Wound repair and replacement of lost or damaged dermal tissue                                       |

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| <b>Codes</b>            | <b>Product name</b>   | <b>Reason(s) for Request (this list may not be all inclusive)</b>                                     |
|-------------------------|---|---|
| Q4327                   | DuoAmnion   | Protective covering or barrier for acute and chronic wounds.  |
| Q4100<br>C9399          | Duraform™ Dural Graft Implant   | Dural repair  |
| Q4100<br>C9399          | DuraGuard®  | Dural repair  |
| Q4100<br>C9399          | DuraGen™ Plus;<br>Duragen® XS Dural Regeneration Matrix                 | Dural repair  |
| Q4100<br>C9399          | DuraMatrix™   | Dural repair  |
| Q4100<br>C9399          | DuraSeal™ Dural Sealant System;<br>DuraSeal™ Spine Sealant System       | Dural repair  |
| Q4100<br>C9399          | Durepair® Regeneration Matrix   | Dural repair  |
| Q4318                   | E-Graft   | Acute and chronic wound covering  |
| Q4297                   | Emerge Matrix   | Protective wound covering and barrier in acute and chronic wounds                                     |
| Q4351                   | Enclose TL Matrix   | Management of full-thickness chronic ulcers and wounds  |
| Q4100<br>C9399          | Endoform Dermal Template™   | Wound care  |
| Q4100                   | ENDURAGEN™  | Soft tissue augmentation, reinforcement and repair in plastic and reconstructive surgery of head/face |
| Q4258                   | Enverse   | Wound care  |
| Q4100<br>C9399          | EpiBurn®  | Wound care  |
| Q4131                   | EpiDex®   | Wound care  |
| Q4278                   | EPIEFFECT   | Wound care  |
| Q4145<br>Q4131<br>Q4186 | EpiFix® Dehydrated Human Amnion/Chorion Membrane Allograft (injectable) | Wound care  |
| Q4272<br>Q4273<br>Q4274 | Esano A,<br>Esano AAA,<br>Esano AC,                                     | Wound care  |

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| <b>Codes</b>   | <b>Product name</b>  | <b>Reason(s) for Request (this list may not be all inclusive)</b>                                       |
|----------------|--|---|
| Q4275          | Esano ACA  |   |
| Q4149          | Excellagen®  | Wound care  |
| Q4136          | E-Z Derm®  | Wound care  |
| Q4100<br>C9399 | FloGraft® Flowable   | Tendonitis, soft tissue trauma  |
| Q4177          | FlowerAmnioFlo™  | Wound care  |
| Q4178          | FlowerPatch™   | Wound care and burn injuries  |
| Q4179          | FlowerDerm™  | Wound care  |
| Q4177<br>Q4178 | FlowerFlo™ (FlowerAmnioFlo™);<br>FlowerAmniopatch™ or FlowerPatch™     | Wound care  |
| Q4206          | Fluid Flow™; Fluid GF™   | Soft tissue repair  |
| Q4172<br>Q4195 | FortaDerm™ Wound Dressing (see<br>PuraPly™ Antimicrobial Wound Matrix) | Wound care  |
| Q4100<br>C1763 | Fortiva™ Porcine Dermis  | Soft tissue reinforcement such as hernia repair   |
| C1781          | GalaFLEX® Surgical Scaffold;<br>GalaFORM™ 3D Scaffold                  | Soft tissue repair and support in plastic and reconstructive surgery                                    |
| Q4111          | GammaGraft®  | Wound care and burn injuries  |
| Q4198          | Genesis® amniotic fluid and membrane                                   | Wound care  |
| C1763<br>C1781 | Gentrix® Surgical Matrix (formerly<br>MatriStem Surgical Matrix)       | Soft tissue reinforcement, plastic, reconstructive, gastrointestinal, urological surgery, hernia repair |
| Q4100<br>C1781 | GORE BIO-A® Fistula Plug;<br>Gore® Bio-A® Tissue Reinforcement         | Anorectal fistulas, soft tissue reinforcement, hernia repair  |
| Q4100<br>C1781 | Gore® Acuseal Cardiovascular Patch                                     | Cardiac, great vessel, and peripheral vascular repair and reconstruction                                |
| Q4113          | GRAFTJACKET Xpress Flowable Soft<br>Tissue Scaffold (FSTS)             | Wound care (deep dermal wounds or diabetic ulcers)  |
|                | GraftRope™   | Allograft tendons and ligaments repair  |
|                | Healadex-P   | Wound care and burns injuries   |
| Q4164          | Helicoll™  | Wound care and burns injuries   |
| Q4224          | Human Health Factor 10 Amniotic Patch™<br>(HHF10-P)                    | Wound care  |
| Q4117          | Hyalomatrix® PA  | Wound careU   |
|                | hyCURE®  | Wound care  |

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| <b>Codes</b>   | <b>Product name</b>   | <b>Reason(s) for Request (this list may not be all inclusive)</b>                            |
|----------------|---|--|
| Q4100<br>C9399 | HydroFix® Vaso Shield   | Vessel guard   |
| Q4262          | Impax Amniotic Membrane (Dual Layer)  | Wound repair and replacement of lost or damaged dermal tissue                                |
| A2001<br>A2013 | Innovamatrix® FS<br>Innovamatrix® AC  | Wound care   |
| A2022<br>A2023 | InnovaBurn or InnovaMatrix  | Wound care   |
| Q4114          | Integra® Flowable Wound Matrix.   | Wound care   |
| Q4126          | InteguPly®  | Tendon repair  |
| Q4171          | Interfyl® Human Connective Tissue Matrix  | Integumental tissue repair   |
|                | Jaloskin®   | Wound care   |
| Q4165          | Keramatrix®   | Wound care and burns injuries  |
| Q4165          | Kerasorb Wound Matrix   | Wound care   |
| Q4158          | Kerecis® Omega3 Wound   | Wound care   |
| A2019          | Kerecis® Omega3 MariGen Shield  | Wound care   |
| Q4202          | Kerxxx Flowable Wound Matrix  | Wound care   |
| Q4291<br>Q4292 | Lamellas XT   | Protective wound covering and barrier in acute and chronic wounds                            |
|                | Leneva Allograft Adipose Matrix (previously marketed under the brand name Renuva) | Wound care   |
|                | LiquidGen™ Tissue Matrix  | Post-surgical wound care (contains growth factors, laminin, fibronectin, and other proteins) |
| Q4100<br>C9399 | Lyoplast® Onlay (Tutopatch®)  | Dural repair   |
| Q4349          | Mantle DL Matrix  | Wound covering for full-thickness acute and chronic wounds                                   |
| Q4158          | MariGen™;<br>Kerecis™ Omega3™ Wound   | Wound care, soft tissue, burn injuries, breast reconstruction, dura mater, hernia repair     |
| Q4100<br>C9399 | MatrACELL®  | Cardiovascular surgery.  |
|                | MatriDerm®  | Dermal Substitute, skin graft, necrotising fasciitis, burns                                  |

## Medica Central Coverage Policy

| Codes          | Product name   | Reason(s) for Request (this list may not be all inclusive)  |
|----------------|--|---|
| Q4201          | Matrion  | Wound care: repair of wounds, tendons, and nerves   |
| Q4118          | MatriStem® Burn Aatrix;<br>MatriStem® Micromatrix;<br>MatriStem® Pelvic Floor Matrix;<br>MatriStem® Surgical Matrix;<br>MatriStem® Wound Matrix. | Wound care  |
| Q4128<br>Q4345 | Matrix HD™   | Wound care, tendon and muscle fascia repair   |
| Q4100          | Medeor™  | Reinforcement/repair of soft tissues (thoracic wall, hernia repair, tendons), reconstructive procedures |
| A4649          | MediHoney®   | Wound care and burns injuries   |
| Q4135          | Mediskin®  | Wound care  |
| Q4205          | Membrane Graft   | Wound care  |
| Q4290          | Membrane Wrap-Hydro™   | Protective barrier in wound care  |
| Q4205          | Membrane Wrap  | Wound care  |
| Q4126          | MemoDerm™  | Wound care, tendon repair   |
|                | Menaflex™, Collagen Meniscus Implant   | Meniscal injuries   |
|                | Meso BioMatrix   | Surgical mesh for plastic and reconstructive applications   |
| Q4175          | Microderm® Biologic Wound Matrix   | Wound care and burns injuries   |
| Q4100<br>C9399 | MiroFlex® (formerly Miromesh®)   | Soft tissue reinforcement: open and laparoscopic hernia repair  |
| Q4118          | MicroMatrix® Biological Mesh   | Wound care  |
| A2005          | Microlyte® Matrix  | Wound care  |
| A2025          | Miro3D, Miro3D Fibers Wound Matrix   | Wound care, designed to fill deep, tunneling, and irregular wound beds                                  |
| Q4175          | MiroDerm® Biologic Wound Matrix  | Wound care  |
| A2002          | Mirrugen Advanced Wound Matrix<br>(Synthetic borate-based glass fiber matrix)  | Wound care  |
| Q4256          | MLG-Complete   | Wound care  |
| Q4328          | MOST (riple layer human amnion-chorion membrane)   | Wound care: protective covering or barrier for acute and chronic wounds.                                |

### Medica Central Coverage Policy

| <b>Codes</b>            | <b>Product name</b>                                | <b>Reason(s) for Request (this list may not be all inclusive)</b>                     |
|-------------------------|--|---|
| Q4226                   | MyOwn Skin   | Wound care  |
| Q4226                   | Nanofactor™ Flow                                   | Arthritis of: Shoulder, hip, midfoot joints, elbow, knee, wrist, fingers, toes, ankle |
| A2021                   | NeoMatriX  | Wound care  |
| Q4176                   | NeoPatch™/Therion                                  | Wound care, tendon injuries, tears, foot ankle injuries                               |
| Q4265<br>Q4266<br>Q4267 | NeoStim Membrane, NeoStim TL Membrane, NeoStimDL   | Wound care  |
| Q4156                   | NEOX® 100 Wound Allograft                          | Wound care  |
| Q4148                   | NEOX®CORD 1k Wound Allograft<br>CLARIX® Cord 1K    | Wound care  |
| Q4148                   | NEOX®CORD RT                                       | Wound care  |
| Q4155                   | NEOX® FLO NuCel™                                   | Wound care  |
| C9352                   | NeuraGen® Nerve Guide                              | Peripheral nerve repair, tendon repair  |
| C9353                   | NeuraWrap™ Nerve Protector                         | Peripheral nerve repair   |
| Q4100<br>C9399          | Neuroflex™   | Peripheral nerve repair, neuromas   |
| C9355                   | NeuroMatrix™                                       | Peripheral nerve repair, neuromas   |
| C9361                   | NeuroMend™   | Peripheral nerve repair, neuromas   |
|                         | NEVELIA® Bi-layer Matrix                           | Wound care  |
| Q4194                   | Novachor   | Wound care  |
| Q4208<br>Q4254          | NovaFix™<br>Novafix® DL                            | Wound care  |
| A2006                   | NovoSorb BTM<br>SynPath synthetic dermal matrix    | Wound care  |
| Q4100<br>C9399          | NuCel®<br>Nucel® Bioactive Amniotic Suspension     | Degenerative disc disease, tendon repair  |
| Q4285<br>Q4286          | NuDYN DL or NuDYN DL MESH<br>NuDYN SL or NuDYN SLW | Wound care  |
| Q4160                   | NuShield® Orthopaedics; NuShield® Spine            | Barrier protection of dura, nerves and tendons  |
| Q4276                   | ORION Amniotic Membrane                            | Wound covering  |



## Medica Central Coverage Policy

| <b>Codes</b>   | <b>Product name</b>   | <b>Reason(s) for Request (this list may not be all inclusive)</b>                      |
|----------------|---|--|
| Q4100<br>C1781 | OrthADAPT™  | Reinforcement, repair and reconstruction of soft tissue in musculoskeletal procedures. |
| Q4100          | Orthoflo  | Cushion and lubrication for joints   |
| Q4100<br>C9399 | OrthoNovis Guard Allograft Membrane   | Wound care   |
| Q4100<br>C9399 | OsseoGuard®   | Oral defects   |
| Q4100<br>C9399 | Ovation®  | Wound healing  |
| Q4353          | Overlay SL Matrix   | Wound covering for full thickness acute and chronic wounds                             |
| Q4100<br>C1781 | Ovitex™   | Reinforce and/or repair soft tissue, repair of hernias and/or abdominal wall defects   |
| Q4173<br>Q4174 | PalinGen® Flow™;<br>PalinGen® FInovoFlo™;<br>Palingen® SportFlow;<br>Palingen® XPlus;<br>PalinGen® Membrane and<br>Hydromembrane™ | Soft tissue repair and wound care  |
| Q4350          | Palisade DM Matrix  | Wound covering for acute and chronic wounds and for postsurgical wound management      |
| Q4100<br>C9399 | Paraderm™ Dermal Tissue Matrix  | Integumental tissue repair   |
| Q4100<br>C9399 | Parietene Macroporous Mesh  | Soft tissue reinforcement  |
| Q4320          | PelloGraft  | Protective covering or barrier for acute and chronic wounds                            |
|                | Pelvicol® (Porcine-derived decellularized collagen)   | Sacrocolpopexy to repair pelvic organ prolapse   |
|                | Pelvisoft®  | Repair of posterior vaginal wall defects, rectocele and cystocele repair               |
| Q4100<br>C1781 | Peri-Guard® Repair Patch  | Soft tissue repair, pericardial and intracardiac repair                                |
| Q4100<br>C9399 | Peri-Strips Dry®  | Staple line reinforcement  |
| C9364          | Permacol™ Surgical Implant  | Soft tissue reinforcement/repair   |

### Medica Central Coverage Policy

| Codes                            | Product name  | Reason(s) for Request (this list may not be all inclusive)  |
|----------------------------------|---|---|
| A2016<br>A1017<br>A2018          | PermeaDerm B;<br>PermeaDerm glove<br>PermeaDerm C   | biosynthetic wound matrix. Porcine gelatin-coated nylon fabric wound dressings for treatment of wounds. |
| C1781                            | Phasix Mesh™;<br>Phasix™ Plug and Patch   | Soft tissue reinforcement/repair  |
| A2015                            | Phoenix wound matrix  | Synthetic matrix for Wound Management   |
| Q4100<br>C1763                   | PhotoFix® Decellularized Bovine Pericardium   | Vascular repair   |
| Q4153                            | Plurivest® and Dermavest®   | Wound care and burns injuries   |
| Q4241                            | PolyCyte®   | Tissue repair   |
| Q4100<br>C9399                   | Preclude® Pericardial Membrane;<br>Preclude® Vessel Guard;<br>Preclude® Dura Substitute       | Reconstruction/repair of the pericardium, dural repair  |
| Q4110                            | Primatrix Dermal Repair Scaffold  | Wound care  |
| Q4100                            | PRISMA Matrix Wound Dressing  | Pressure ulcer  |
| J3590                            | Pro3-C Amniotic Fluid   | Wound care  |
| Q4100<br>C9399                   | Pro3™ Membrane  | Wound care  |
| Q4244                            | Procenta™   | Wound care  |
| Q4222                            | ProgenaMatrix™  | Wound care  |
| Q4100<br>C9399                   | ProLayer Acellular Matrix (xenograft)   | Wound care  |
| Q4174                            | ProMatrX ACF  | Wound care  |
| Q4100                            | Promogran Prisma™ Matrix  | Bind and protect the functionality of growth factors (e.g., PDGF) in hostile proteolytic environments   |
| Q4100<br>C9399                   | Promote™ Amnio-Frt™;<br>Promote™ Amnio F™;<br>Promote™ AmnioStrip™                            | Wound care  |
| Q4100<br>C9399                   | Puracol®  | Wound care  |
| Q4172<br>Q4195<br>Q4196<br>Q4197 | PuraPly™ Wound Matrix (previously FortaDerm™)<br><br>PuraPly™ AM (Antimicrobial Wound Matrix) | Wound care  |

### Medica Central Coverage Policy

| <b>Codes</b>   | <b>Product name</b>   | <b>Reason(s) for Request (this list may not be all inclusive)</b>       |
|----------------|---|---|
| Q4100          | Puros® Dermis   | Periodontal/peri-implant soft tissue management                         |
| Q4100<br>C9399 | PX50® and X50® Plus   | Damaged or inadequate tissue repair (orthopedic and podiatric uses)     |
| Q4347          | Rampart DL Matrix   | Wound covering for acute and chronic wounds                             |
| Q4296          | Rebound Matrix  | Protective wound covering and barrier in acute and chronic wounds       |
| Q4314          | Reeva FT  | Protective wound covering and barrier in acute and chronic wounds       |
|                | Regeneten Bioinductive implant  | Reconstructive surgery (Rotator cuff tears and other shoulder injuries) |
| Q4315          | RegeneLink Amniotic Membrane Allograft                                  | Protective covering or barrier for internal and external tissue defects |
| Q4255          | REGUaRD™  | Wound care  |
| Q4257          | Relese  | Wound care  |
| Q4321          | RenoGraft   | Protective wound covering and barrier in acute and chronic wounds       |
|                | ReNu® (Cryopreserved amniotic membrane suspension allograft) Injectable | Management of symptoms associated with knee osteoarthritis (OA)         |
| J3590          | Renuva® (allograft adipose matrix)                                      | Restore volume in the face, hands and body                              |
| C1762          | Repliform®  | Integumental tissue repair; pelvic floor repair                         |
| Q4143          | Repriza®  | Reconstructive surgery (breast reconstruction, abdominal wall repair)   |
| A2024          | Resolve Matrix<br>(Previous name: Meso Wound Matrix/meso BioMatrix)     | Wound care  |
| Q4100<br>C1781 | Restore® Orthobiologic Soft Tissue Implant                              | Soft tissue reinforcement   |
| Q4191<br>Q4192 | Restorgin™ Amnion Patch<br>Restorgin™ Amniotic Fluid                    | Wound care  |
| Q4191<br>A2007 | Restrata™ Wound Matrix or Restrata MiniMatrix                           | Wound care  |
| Q4180          | Revita®   | Wound care  |
| Q4157          | Revitalon®  | Wound care  |

### Medica Central Coverage Policy

| <b>Codes</b>   | <b>Product name</b>                                      | <b>Reason(s) for Request (this list may not be all inclusive)</b>                                       |
|----------------|--|---|
| Q4100<br>C9399 | RX® Flow   | Connective tissue repair  |
| Q4100<br>C1781 | RX® Membrane   | Soft tissue repair  |
| Q4308          | Sanopellis   | Protective covering or barrier for internal and external tissue defects                                 |
| Q4319          | SanoGraft  | Protective covering or barrier for internal and external tissue defects                                 |
| Q4100<br>C9399 | Seamguard®   | Staple line reinforcement   |
| Q4348          | Sentry SL Matrix   | Wound covering for acute and chronic wounds   |
| Q4100<br>C1781 | SERI® Surgical Scaffold                                  | Transitory scaffold for soft tissue support and repair  |
| Q4346          | Shelter DM Matrix  | Wound covering for acute and chronic wounds and for postsurgical wound management                       |
| Q4260          | Signature APatch   | Wound care  |
| Q4329          | Singlay  | Protective covering or barrier for internal and external tissue defects                                 |
| Q4100<br>C9399 | SJM™ Pericardial Patch                                   | Pericardial repair  |
| Q4200          | Skin TE (autologous skin)                                | Wound care  |
| Q4100<br>C1781 | SportMesh™   | Soft tissue reinforcement: rotator cuff   |
| Q4100<br>C9399 | SteriMatrix™   | Repair damaged bones or ligaments   |
| Q4100<br>C9399 | SteriSheild™   | Soft tissue reinforcement/repair  |
|                | StrataGraft®   | Severe burns and complex skin defects   |
| Q4133<br>C9399 | Stravix®; Stravix PL®                                    | Integumental tissue repair, acute and chronic wound cover or surgical wrap                              |
| Q4220          | SureDerm®  | Soft tissue repair  |
| Q4233          | Surgenex / Surfactor / Nudyn Injectable                  | Wound healing, soft tissue repair   |
| C9358<br>C9360 | SurgiMend® PRS Meshed Collagen Matrix (bovine xenograft) | Breast reconstruction, plastic and reconstructive surgery, muscle flap reinforcement, and hernia repair |

### Medica Central Coverage Policy

| <b>Codes</b>                     | <b>Product name</b>   | <b>Reason(s) for Request (this list may not be all inclusive)</b> |
|----------------------------------|---|---|
| A2011                            | Supra SDRM  | Wound care  |
| A4649<br>A2012                   | Suprathel®  | Partial-thickness burn injuries dressing                          |
| Q4209<br>Q4263<br>Q4268<br>Q4269 | SurGraft® FT;<br>SurGraft® TL;<br>SurGraft® XT;<br>SurGraft® FT                                 | Diabetic wounds, burns, and ocular repair                         |
| Q4218<br>Q4219<br>Q4183          | surgiGRAFT™;<br>SurgiGRAFT-DUAL;<br>SurgiCORD®  | Wound care  |
| Q4100<br>C9399                   | Symbotex™ Composite Mesh  | Soft tissue reinforcement (e.g., hernia repair)                   |
| A2009                            | Symphony  | Wound care  |
| Q4100<br>C1781                   | SYNTHECEL® Dura Repair  | Dural repair  |
| Q4261                            | TAG (Amniotic allograft)  | Wound care  |
| Q4127                            | Talymed™  | Wound care  |
| Q4100<br>C9399                   | tarSys™ Acellular Dermal Matrix   | Wound care, eyelid reconstruction                                 |
| C9356                            | TenoGlide™  | Tendon repair   |
| Q4146                            | TenSIX™ Acellular Dermal Matrix   | Wound care, tendon repair   |
|                                  | TheraForm™ Standard/Sheet   | Wound care, burn injuries   |
| A2008                            | TheraGenesis  | Wound care  |
| Q4146<br>C1781                   | TissueMend®   | Soft tissue repair, tendon repair                                 |
| Q4330                            | TOTAL (Human amnion-chorion allograft)  | Wound care  |
| Q4146<br>C1781                   | Tornier® BioFiber Absorbable Biological Scaffold;<br>Tornier® Collagen Coated BioFiber Scaffold | Soft and/or hard tissue repair                                    |
| Q4100<br>Q4126                   | TranZgraft™   | Various surgical and wound repair applications                    |
| Q4167                            | TruSkin™  | Wound care  |
| C1763                            | Tutopatch and Tutomesh  | Soft tissue reinforcement, pericardial repair                     |

### Medica Central Coverage Policy

| <b>Codes</b>   | <b>Product name</b>  | <b>Reason(s) for Request (this list may not be all inclusive)</b>  |
|----------------|--|--|
| Q4100<br>C9399 | Unite Biomatrix™   | Wound care   |
| Q4100<br>C9399 | Vascu-Guard®   | Peripheral vascular reconstruction (including carotid, renal, iliac, femoral, and tibial blood vessels)            |
| Q4252          | Vendaje® Amniotic Membrane   | Burn care, wound care  |
| Q4100<br>C9399 | VersaShield™   | Wound care; soft tissue covering   |
| Q4100<br>C9354 | Veritas® Collagen Matrix   | Soft tissue reinforcement/repair   |
|                | VersaWrap®   | Soft tissue reinforcement/tendon repair (flexor, rotator cuff, patellar, Achilles, biceps, quadriceps, and others) |
| Q4100<br>C1781 | Viaflow™/Viaflow C   | Connective tissue repair   |
| Q4251          | VIM™ Human Amniotic Membrane                                       | Wound care   |
| Q4317          | VitoGraft  | Wound care   |
| Q4163          | WoundEx™   | Wound care   |
| Q4162          | WoundEx® Flow  | Integumental tissue repair   |
| Q4217          | WoundFix™ Membrane;<br>WoundFix™ Membrane Plus;<br>WoundFix™ Xplus | Wound care   |
| Q4326          | WoundPlus membrane   | Wound covering   |
| Q4353          | Xceed™ TL Matrix   | Wound care   |
| Q4280          | Xcell Amnio Matrix   | Wound care   |
| Q4234          | Xcellerate®  | Burn care, wound care  |
| C1781          | XenMatrix™ Surgical Graft  | Soft tissue reinforcement/repair   |
| C1763          | Xenform®   | Soft tissue reinforcement/repair   |
| Q4142          | XCM Biologic™ Tissue Matrix  | Soft tissue reinforcement/repair   |
| Q4100          | Xelma®   | Soft tissue reinforcement/repair   |
| Q4100<br>C1781 | XenoSure® Biolog   | Cardiac and vascular reconstruction/repair   |
|                | X-Repair   | Tendon and other soft-tissue injuries  |
| Q4204          | Xwrap™ (Hydro, DRY, and ECM)                                       | Wound care   |



### Medica Central Coverage Policy

| Codes | Product name              | Reason(s) for Request (this list may not be all inclusive)               |
|-------|---------------------------|--|
| Q4163 | WoundEx® Membrane         | Diabetic foot ulcers, Venous leg ulcers, Burn wounds, Chronic leg wounds |
| Q4253 | Zenith™ Amniotic Membrane | Burn care<br>Wound care  |
| Q4100 | Zenapro®                  | Soft tissue reinforcement/repair   |