MEDICAL COVERAGE POLICY	
SERVICE:	**Biologicals for Wound Care and Procedures**
Policy Number:	**210**
Effective Date:	**03/01/2025**
Last Review:	**01/13/2025**
Next Review:	**01/13/2026**

Important note: *Unless otherwise indicated, medical policies will apply to all lines of business. Medical necessity as defined by this policy does not ensure the benefit is covered. This medical policy does not replace existing federal or state rules and regulations for the applicable service or supply. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan documents. See the member plan specific benefit plan document for a complete description of plan benefits, exclusions, limitations, and conditions of coverage. In the event of a discrepancy, the plan document always supersedes the information in this policy.*

SERVICE: Biologicals for Wound Care and Procedures

PRIOR AUTHORIZATION: Required in some instances

POLICY: This policy outlines the coverage of a heterogeneous group of products/substances that have been used to treat conditions such as diabetic and venous wound ulcers, burns, arthritic conditions, and fractures. The policy finds a vast majority of these treatments investigational in nature.

Note: Unless otherwise indicated (see below), this policy will apply to all lines of business.

For Medicare plans, please refer to appropriate Medicare NCD (National Coverage Determination) or LCD (Local Coverage Determination). **Specific NCDs / LCDs to be referenced are listed under the specific service sections throughout this policy.** Medicare NCD or LCD specific InterQual criteria may be used when available. If there are no applicable NCD or LCD criteria, use the criteria set forth below.

For Medicaid plans, please confirm coverage as outlined in the Texas Medicaid Provider Procedures Manual | TMHP (TMPPM), **9.2.79.2.3 Second-Line Wound Care Therapy.** If there are no applicable criteria to guide medical necessity decision making in the TMPPM, use the criteria set forth below.

Biologics (not medications) used in procedures include:
- Autologous blood-derived growth factors, such as, Platelet Rich Plasma (PRP)
- Stem cells and Mesenchymal stem cells (MSC)
- Recombinant human bone morphogenic protein (rhBMP)
- Amniotic membrane transplant (AMT) for ophthalmologic procedures
- Skin Substitutes/Dermal matrix / cellular- and tissue-based products (SS/DM/CTP)

A. **Autologous blood-derived growth factors, such as, Platelet Rich Plasma (PRP)**
   1. For **Medicare** lines of business, BSWHP may consider autologous blood-derived growth factors, such as Platelet Rich Plasma (PRP), **medically necessary** when used for the wound care indications listed in NCD 270.3 - Blood-Derived Products for Chronic Non-Healing Wounds. Use Medicare InterQual product for criteria where applicable for Medicare lines of business.

2. For **Medicaid** lines of business, BSWHP may consider autologous blood-derived growth factors, such as Platelet Rich Plasma (PRP), **medically necessary** when the criteria for indications and use have been met in the Texas Medicaid Provider Procedures Manual | TMHP (TMPPM), **9.2.79.2.3 Second-Line Wound Care Therapy**.
3. BSWHP considers autologous blood-derived growth factors, such as Platelet Rich Plasma (PRP), **experimental and investigational** for all indications, for **all other lines of business.**

B. **Stem Cells and Mesenchymal Stem Cells (MSC)**
1. BSWHP considers **mesenchymal stem cell therapy experimental and investigational** for treatment of orthopedic indications for **all lines of business**.
2. BSWHP considers **brain tissue transplantation, or stem-cell neuro-transplantation experimental and investigational** for treatment of Parkinson's Disease (embryonic or fetal allograft or auto-transplantation) for **all lines of business**.

C. **BSWHP recombinant human Bone Morphogenic Protein (rhBMP)**
1. Currently, only rhBMP-2 has FDA approval for specific uses. The InFUSE Bone Graft and InFUSE MASTERGRAFT consist of rhBMP-2 (dibotermin alfa) on an absorbable collagen sponge carrier.
   a. BSWHP may consider the **InFUSE Bone Graft medically necessary** for:
      i. **Spinal fusion with degenerative disc disease** when **ALL of the following criteria are met:**
         - Skeletally mature member
         - Single-level degenerative disc disease from L2 to S1, with no more than a Grade I spondylolisthesis or Grade I retrolisthesis at the involved level
         - Will undergo an anterior or oblique approach (ALIF, DLIF, XLIF, LLIF)
         - Has failed 6 months of conservative treatment
      ii. **Open fracture of the tibial shaft** in the skeletally mature member who has been stabilized with intramedullary nail fixation after appropriate wound management within 14 days of the initial fracture.
   b. BSWHP may consider the **InFUSE MASTERGRAFT medically necessary** for **posterolateral lumbar spine pseudoarthrosis** when **ALL of the following criteria are met:**
      i. Skeletally mature member
      ii. Autologous bone and / or bone marrow harvest is not feasible OR not expected to promote fusion (e.g., diabetic, smoker)
      iii. Will undergo two or more levels of intervention via a posterolateral approach
2. BSWHP considers the use of **rhBMP-2 and other rhBMPs experimental, investigational, and unproven for all other indications**, including, but not limited to:
   a. Cervical spinal fusion
   b. Ankle fusions

c. Posterior lumbar interbody fusion (PLIF) or transforaminal lumbar interbody fusion (TLIF)
d. Management of early-stage osteonecrosis of the vascular head or femoral shaft
e. Adjunct to distraction osteogenesis (Iliazarov Procedure)
f. Craniofacial applications including, but not limited to, periodontal defect regeneration, cleft palate repair, cranial defect repair, and restoration and maintenance of the alveolar dental ridge

D. **Amniotic and Placental Derived Products**
1. BSWHP considers **amniotic and placental derived products experimental and investigational for non-wound care indications, including orthopedic indications, for all lines of business.** Non-covered products include, but are not limited to, AlloStem® Cellular Bone Allograft (AlloSource), NuCel, Map3, Osteocel Plus, Trinity Evolution Matrix, Cellentra, RegenexxSD. LCD L39624
2. BSWHP may consider **Amniotic Membrane Transplantation medically necessary** for the following **ophthalmologic conditions** after failure of conservative treatment (list is not all-inclusive of coverable conditions):
   a. Chemical and thermal injuries
   b. Conjunctivochalasis
   c. Conjunctival surface reconstruction
   d. Corneal ulceration / perforation
   e. Herpes zoster ophthalmicus
   f. Limbal stem cell deficiency (partial or total): combined with stem cell graft
   g. Persistent epithelial defects
   h. Pterygium surgery
   i. Stevens-Johnson Syndrome
   j. Symblepharon lysis
   k. Symptomatic bullous keratopathy
   l. Trabeculectomy: bleb leakage or revision
   m. Neurotrophic keratitis
   n. Partial limbal stem cell deficiency with extensive diseased tissue where selective removal alone is not sufficient

E. BSWHP may consider **Select Skin Substitutes / Dermal matrix / Cellular Tissue based Products (CTPs)** may be considered **medically necessary** in certain situations outlined in the following LCDs:
1. LCD L35041 Application of Bioengineered Skin Substitutes to Lower Extremity Chronic Non-Healing Wounds
2. LCD L35125 Wound Care

F. **Biologicals Coverage Summary**

This list is not an all-inclusive list of approvable materials. Some materials may become non-covered as evolving evidence becomes available. BSWHP will continue to review clinical evidence and may modify this list as indicated as new clinical evidence becomes available.

Wound Care / Burn Material	Code	Conditions
AlloDerm	Q4116	Wound healing in breast reconstruction, partial
Artiss	C9250	Burns
Affinity1 square cm	Q4159	
Alloskin	Q4115	
Alloskin RT	Q4123	
Alloskin AC	Q4141	
Amnioband	Q4168	Chronic partial / full-thickness ulcers of the lower extremities
Apligraf	Q4101	Venous ulcers, diabetic ulcers
Artacent ac 1 sq cm	Q4190	
Artacent wound, per sq cm	Q4169	
Biobrane Biosyntheic Dressing	Q4100	Burns, temporary covering of superficial / partial thickness
Bio-connekt per square cm	Q4161	
Biodfence 1cm	Q4140	
Biovance 1 square cm	Q4154	
Dermacell	Q4122	
Derma-gide, 1 sq cm	Q4203	
Dermagraft	Q4106	Epidermolysis bullosa, diabetic ulcers (> 6-week duration)
Dermavest, polycy sq cm	Q4153	
Epicel	Q4100	Deep burns when >30% BSA affected
Epicord 1 sq cm	Q4187	Neuropathic / diabetic foot ulcers (> 6-week duration, no capsule / tendon / bone exposure)
Epifix	Q4186	Diabetic ulcers
Ezderm	Q4136	
Flexhd/allopatchhd/matrixhd	Q4128	
Grafix core	Q4132	Diabetic ulcers
Grafix prime	Q4133	Diabetic ulcers
Graftjacket	Q4107	Venous ulcers, diabetic ulcers
Hmatrix	Q4134	
Integra® Bilayer Matrix Wound Dressing	Q4104	Burns
Integra® Dermal Regeneration Template	Q4105	Burns, diabetic ulcers
Integra® Matrix	Q4108	

Matristem micromatrix	Q4118	
Miroderm	Q4175	
Nushield 1 square cm	Q4160	
Oasis Burn Matrix	Q4103	Burns
Oasis tri-layer wound matrix	Q4124	
Oasis Wound Matrix	Q4102	Venous ulcers, diabetic ulcers
OrCel	Q4100	Recessive dystrophic epidermolysis bullosa, donor site
Palingen or palingen xplus	Q4173	
Revita, per sq cm	Q4180	
Revitalon 1 square cm	Q4157	
Surgigraft, 1 sq cm	Q4183	
Theraskin	Q4121	
TransCyte	Q4182	Surgically excised full-thickness thermal burn wounds and deep partial-thickness thermal burn wounds before autograft placement
Woundex, bioskin, per sq cm	Q4163	
Amniotic Membrane for ocular surface	V2790	For ophthalmologic conditions – see indications above

All other products and materials are considered experimental, investigational (E&I), or unproven, because there is inadequate evidence in the peer-reviewed medical literature to support their clinical effectiveness. Some materials may become approvable as evolving evidence becomes available. BSWHP will continue to review clinical evidence and as indicated may modify the below list of experimental, investigational, or unproven materials (**list is not an all-inclusive).**

Code	Wound Care / Burn Material
A2001	InnovaMatrix AC, per sq cm
A2002	Mirragen Advanced Wound Matrix, per sq cm
A2004	XCelliStem, per sq cm
A2005	Microlyte Matrix, per sq cm
A2006	NovoSorb SynPath dermal matrix, per sq cm
A2007	Restrata, per sq cm
A2008	TheraGenesis, per sq cm
A2009	Symphony, per sq cm
A2010	Apis, per sq cm
A2011	Supra SDRM, per sq cm
A2013	Innovamatrix FS, per sq cm
C1832	Autograft suspension, including cell processing and application, and all system components

C9356	Tendon, porous matrix of cross-linked collagen and glycosaminoglycan matrix (TenoGlide)
C9358	Dermal substitute, native, non-denatured collagen (SurgiMend Collagen Matrix)
C9360	Dermal substitute, native, non-denatured collagen, neonatal bovine origin (SurgiMend Collagen Matrix)
C9363	Skin substitute (Integra Meshed Bilayer Wound Matrix), per sq cm
C9364	Porcine implant, Permacol
Q4110	Primatrix
Q4111	Gammagraft
Q4112	Cymetra, injectable
Q4113	GRAFTJACKET XPRESS
Q4114	Integra Flowable Wound Matrix
Q4117	Hyalomatrix
Q4119	MatriStem wound matrix
Q4125	Arthroflex
Q4126	Memoderm
Q4127	Talymed
Q4129	Unite biomatrix
Q4130	Strattice TM
Q4135	Mediskin
Q4137	AmnioExcel
Q4138	Biodfence dryflex
Q4139	Amniomatrix or biodmatrix, injectable
Q4142	XCM biologic tissue matrix
Q4143	Repriza
Q4145	EpiFix injectiable
Q4146	TenSIX
Q4147	Architect
Q4148	Clarix cord or Neox cord
Q4149	Excellagen
Q4150	Allowrap DS or dry
Q4151	Guardian
Q4152	DermaPure
Q4155	Neoxflo or clarixflo
Q4156	Clarix 100 or Neox 100
Q4158	Kerecis Omega 3
Q4164	Helicoll

Q4165	Keramatrix
Q4166	Cytal
Q4167	Truskin
Q4168	Amnioband
Q4170	Cygnus
Q4171	Interfyl
Q4178	Floweramniopatch
Q4195 Q4196	Puraply or puraply am
Q4174	PalinGen or ProMatrX
Q4176	NeoPatch
Q4177	FlowerAmnioFlo
Q4179	FlowerDerm
Q4181	Amnio Wound
Q4182	Transcyte
Q4188	AmnioArmor
Q4205	Membrane Graft or Membrane Wrap
Q4206	Fluid Flow or Fluid GF
Q4208	Novafix
Q4209	SurGraft
Q4210	Axolotl Graft or Axolotl DualGraft
Q4211	Amnion Bio or AxoBioMembrane
Q4212	AlloGen
Q4213	Ascent
Q4214	Cellesta Cord
Q4215	Axolotl Ambient or Axolotl Cryo
Q4216	Artacent Cord
Q4217	WoundFix, BioWound, WoundFix Plus, BioWound Plus, WoundFix Xplus or BioWound Xplus
Q4218	SurgiCORD
Q4219	SurgiGRAFT-DUAL
Q4220	BellaCell HD or Surederm
Q4221	Amnio Wrap2
Q4222	ProgenaMatrix
Q4226	MyOwn Skin, includes harvesting and preparation procedures

BACKGROUND:

Platelet Rich Plasma (PRP)
PRP has been investigated as an adjunct to a variety of periodontal, reconstructive, and orthopedic procedures. In addition, platelet-rich plasma has also been proposed as a primary treatment of miscellaneous conditions such as epicondylitis, plantar fasciitis, Dupuytren's contracture, and tendon injury. Typically, the platelet-rich material is injected into joint area with the goal of accelerating the healing process.

A meta-analysis of 10 trials assessing the effect of PRP injections in patients with knee OA found a significant difference in pain scores in the PRP-treated groups (8). However, the majority of the trials revealed a high likelihood of biases, and only one of the trials compared PRP injections with placebo. No trials have examined the structural effects of PRP in OA joints. There is a lack of standardization of the preparations of PRP amongst the trials, with varying concentration of platelet, frozen versus fresh preparations, and the filtration of white cells. The clinical trials have yet to conclusively demonstrate efficacy of the treatment. The available controlled studies do not provide consistent evidence that PRP improves outcomes in patients with ACL injury. Three RCTs found that PRP did not provide any significant benefits as a treatment for rotator cuff injuries, Achilles tendinopathy, or Achilles tendon rupture. A 2014 systematic review of PRP in musculoskeletal injuries, as well as subsequent trials of PRP in tendinopathy showed no clear benefit.

Skin substitutes / Dermal matrix
Skin substitutes can be biological or synthetic substitutes. These products may be derived from allogeneic, xenographic, synthetic, or any combination of these. The biological skin substitutes have a more intact extracellular matrix structure, while the synthetic skin substitutes can be synthesized on demand. Both have advantages and disadvantages. The biological skin substitutes form a more natural new dermis and allow epithelialization because of the presence of a basement membrane.

Two Hayes assessments of skin substitutes for VLUs and DFUs showed some evidence, albeit weak, that skin substitutes may improve healing of both types of wounds.

Dermal matrices are considered a standard-of-care with breast reconstruction, with fewer complications and better results. Early literature focused on AlloDerm brand of acellular dermal matrix, as the initial product. Recent literature comparing acellular dermal matrix products conclude there is no significant difference among products (see, e.g., Ibrahim, et al., 2013; Cheng, et al., 2012).

Mesenchymal Stem Cells

Mesenchymal stem cells (MSCs) are multipotent cells (also called "stromal multipotent cells") have the capability to differentiate into a variety of tissue types, including organs, trabecular bone, tendon,

articular cartilage, ligaments, muscle, and fat. Mesenchymal stem cells have been classically obtained from the bone marrow and have been shown to differentiate into various cell types, including osteoblasts, chondrocytes, myocytes, adipocytes, and neuronal cells. Potential uses of MSCs for orthopedic applications include treatment of damaged bone, cartilage, ligaments, tendons, and intervertebral discs. The proposed benefits of MSC therapy are improved healing and possible avoidance of surgical procedures with protracted recovery times.

Although processing techniques vary, and the optimal number of MSCs to be transplanted/seeded has not been established, following autologous bone marrow collection MSCs are either concentrated for direct injection, or cultured and incubated. Once cultured the MSCs can be mixed with biomaterials, such as gels or pastes; the biomaterials hold the cells in suspension and provide a matrix for filling defects. MSCs can also be seeded on scaffolds and have been investigated when used with a support matrix for implantation (e.g., tissue engineered).

In theory, MSCs are responsive to osteogenic growth factors and aid in the healing of bone. Nevertheless, evidence in the published peer-reviewed scientific literature evaluating the use of MSCs to enhance bone healing consists mainly of animal trials and a paucity of human trials. At present, the evidence is insufficient to support improved clinical outcomes, when used alone, added to other biomaterials, or as cultured/seeded on a support matrix.

The FDA regulates human cells and tissues intended for implantation, transplantation, or infusion through the Center for Biologics Evaluation and Research, under Code of Federal Regulation, Title 21, parts 1270 and 1271. MSCs are included in these regulations. Concentrated autologous MSCs do not require approval by the U.S. Food and Drug Administration (FDA).

Currently there are no allogeneic MSC therapies or devices that are approved for marketing by the FDA. However, there are products containing mesenchymal stem cells that are commercially available for orthopedic indications, which include, not all-inclusive:

- AlloStem® Cellular Bone Allograft (AlloSource, Centennial, CO): Comprised of adipose derived mesenchymal stem cells with partially demineralized allograft bone.
- NuCel® (NuTech Medical, Birmingham, AL): Derived from amniotic membrane
- Map3™ (rti surgical): Contains cortical cancellous bone chips, DBM, and multipotent adult progenitor cells.
- Osteocel Plus® (NuVasive): DBM combined with viable MSCs that have been isolated from allogeneic bone marrow.
- Trinity Evolution Matrix™ (Orthofix): DBM combined with viable MSCs that have been isolated from allogeneic bone marrow.
- Cellentra™ VCBM (Biomet®): An allograft that is cryopreserved containing MSCs, osteoprogenitor cells, and pre-osteoblasts.
- RegenexxSD® (Same Day Stem Cell Procedure): A procedure involving autologous bone marrow that is concentrated and a super-platelet mix is added, and the final product is injected into the

affected site.
- RegenexxAD® (Adipose Derived Stem Cell Procedure): A procedure that combines RegenexxSD with stem cells derived from adipose tissue, the final product is then injected into an affected site.
- VIA® Form and VIA® Graft (Vivex Biomedical)8: This is a family of products referred to as "cellular bone matrices" which are viable allogeneic bone allografts with MSC and bone components. These products are intended for use in bone remodeling in a number of applications including spine, upper extremity, foot/ankle, oral/maxillofacial and orthopedic oncology.
- ViviGen® (DePuy)9: This product is a cellular bone matrix is comprised of cryopreserved viable cortical cancellous bone matrix and demineralized bone. ViviGen® is intended for repair or reconstruction of musculoskeletal defects.

MSC therapy has been proposed as a treatment option for orthopedic indications that include but are not limited to the following:
- Knee: Arthritis, meniscus tears, tendon and ligament tears, overuse injuries and other conditions
- Hip: Injuries, arthritis, bursitis, and other degenerative conditions
- Shoulder: Arthritis, rotator cuff tears, and other shoulder conditions
- Spine and cervical conditions: Back pain, pain from bulging or herniated discs, degenerated discs, or pain from an extruded or torn disc
- Elbow: Injuries, overuse conditions and arthritis (tendon and ligament issues) • Hand/Wrist: Arthritis and other conditions
- Foot/Ankle: Ligament tears, sprains and instability of the ankle joint, an alternative to fusion or replacement surgery of the ankle
- Non-union fractures

The American Academy of Orthopedic Surgeons (2007) provides information on stem cells:

> Bone marrow stromal cells are mesenchymal stem cells that, in the proper environment, can differentiate into cells that are part of the musculoskeletal system. They can help to form trabecular bone, tendon, articular cartilage, ligaments and part of the bone marrow.

The statement was revised in 2017:
"The increasing shift to therapeutic biologic products for restoring structure and function presents new questions of safety and effectiveness. No longer reserved for treating trauma and soft tissue injuries, biologic therapies are now explored as options for osteoarthritis. As we note in the statement "Innovation and New Technologies in Orthopaedic Surgery," surgeons must be aware of the scientific basis for the different treatment options offered to their patients, including the benefits and risks. The varying regulatory pathways by which biologic therapies come to market require the additional burden for surgeons to become familiar with the Food and Drug Administration's current thinking with respect to the source, retrieval and/or manufacturing methods, processing, storage, and use of these products, whether alone or as part of combination products.

The American Academy of Orthopaedic Surgeons (AAOS) believes that surgeons should be cognizant of the risks, benefits, regulatory status and labeled indications of the products they use. Unlike devices, the effects of these products may not be limited to the duration of their implantation. Autogenous products may be subject to regulatory review."

Recombinant human Bone Morphogenic Protein rhBMPs
Osteogenic proteins or bone morphogenic proteins (BMPs) are bone-matrix polypeptides that induce a sequence of cellular events leading to the formation of new bone. Some of the potential clinical applications of BMPs are: (i) as a bone graft substitute to promote spinal fusion and to aid in the incorporation of metal implants, (ii) to improve the performance of autograft and allograft bone, and (iii) as an agent for osteochondral defects.

A Hayes review of rhBMP-2 compared to autograft showed some evidence that rhBMP-2 quickens lumbar and cervical fusions. Similarly, a systematic review in 2020 showed the efficacy of rhBMP-2 lumbar fusion.

Amniotic Membrane Transplant
Ocular injuries due to trauma or disease that do not respond to conservative treatment may benefit from the use of AMT. The amniotic membrane has properties that are helpful in wound healing, particularly in ocular injuries. The amniotic membrane is the inner layer of the fetal sac, a stromal matrix, with a thick collagen layer and a single layer of epithelium. It suppresses growth factor to minimize scar formation and promotes cellular migration for improved healing.

MANDATES: None

CODES:
Important note: *Due to the wide range of applicable diagnosis codes and potential changes to codes, an inclusive list may not be presented, but the following codes may apply. Inclusion of a code in this section does not guarantee that it will be reimbursed, and patient must meet the criteria set forth in the policy language.*

CPT Codes:	15271 - 15278 - Application of skin substitute
CPT Not Covered	
HCPCS Codes	C9250 – Artiss Q4159 – Affinity1 Q4115 – Alloskin Q4123 – Alloskin Q4141 - Alloskin ac, 1 cm Q4188 - Amnioarmor 1 sq cm Q4151 - Amnioband, guardian 1 sq cm Q4137 - Amnioexcel biodexcel 1sq cm Q4101 - Apligraf

	Q4147 - Architect ecm px fx 1 sq cm Q4190 - Artacent ac 1 sq cm Q4169 - Artacent wound, per sq cm Q4100 - Biobrane Biosyntheic Dressing Q4161 -Bio-connekt per square cm Q4140 - Biodfence 1cm Q4154 - Biovance 1 square cm Q4166 - Cytal, per square centimeter Q4122 - Dermacell Q4203 - Derma-gide, 1 sq cm Q4106 - Dermagraft Q4152 - Dermapure 1 square cm Q4153 - Dermavest, plurivest sq cm Q4100 - Epicel Q4187 - Epicord 1 sq cm Q4186 - Epifix Q4136 - Ezderm Q4128 - Flexhd/allopatchhd/matrixhd Q4178 - Floweramniopatch, per sq cm Q4111 - Gammagraft Q4132 - Grafix core Q4133 - Grafix prime Q4107 - Graftjacket Q4164 - Helicoll, per square cm Q4134 - Hmatrix Q4117 - Hyalomatrix Q4104 - Integra® Bilayer Matrix Wound Dressing Q4105 - Integra® Dermal Regeneration Template Q4108 - Integra® Matrix Q4165 - Keramatrix, per square cm Q4158 - Kerecis omega3, per sq cm Q4118 - Matristem micromatrix Q4135 - Mediskin Q4126 - Memoderm/derma/tranz/integup Q4175 - Miroderm Q4156 - Neox 100 or clarix 100 Q4148 - Neox neox rt or clarix cord Q4160 - Nushield 1 square cm Q4103 - Oasis Burn Matrix Q4124 - Oasis tri-layer wound matrix Q4102 - Oasis Wound Matrix Q4100 - OrCel Q4173 - Palingen or palingen xplus Q4110 – Primatrix Q4195 - Puraply 1 sq cm Q4196 - Puraply am 1 sq cm

	Q4180 - Revita, per sq cm Q4157 - Revitalon 1 square cm Q4183 - Surgigraft, 1 sq cm Q4127 - Talymed Q4146 - Tensix, 1cm Q4121 - Theraskin Q4163 - Woundex, bioskin, per sq cm V2790 - Amniotic membrane
ICD10 codes	Platelet Rich Plasma M72.2 - Plantar fascial fibromatosis M76.5 - Patellar tendinitis M76.6 - Achilles tendinitis M77.1 - Lateral epicondylitis S46.0 - Injury of tendon of the rotator cuff of shoulder S76.1 - Injury of quadriceps tendon and muscle S83.4 - Sprain and strain involving fibular collateral ligament of knee S83.5 - Sprain and strain involving anterior cruciate ligament of knee S86.0 - Injury of Achilles tendon Bone morphogenetic protein M45.x* - Ankylosing spondylitis M47.x* - Spondylosis M50.x* - Cervical disc disorders M51.x* - Other intervertebral disc disorders S82.x* - Fracture of tibia Alloderm: C50.011 - C50.929 Malignant neoplasm of breast C79.81 - Secondary malignant neoplasm of breast D05.00 - D05.92 Carcinoma in situ of breast Other: T20.011+ - T25.799+ - Burns E08.621 - Diabetes mellitus due to underlying condition with foot ulcer E09.621 - Drug or chemical induced diabetes mellitus with foot ulcer E10.621 - Type I diabetes mellitus with foot ulcer E11.621 - Type II diabetes mellitus with foot ulcer E13.621 - Other specified diabetes mellitus with foot ulcer I87.311 - I83.319 - Chronic venous hypertension with ulcer I87.331 - I87.339 - Chronic venous hypertension with ulcer and inflammation *“x” is a range of codes; code dependent on specific diagnosis*

POLICY HISTORY:

Status	Date	Action
New	03/27/2014	New policy
Reviewed	04/09/2015	Minor corrections
Reviewed	04/14/2016	Updated coverage
Reviewed	04/18/2017	Revised coverage criteria.
Reviewed	04/03/2018	Modified list of materials covered.
Updated	05/01/2018	Added to list of materials not covered: TenoGlide
Updated	06/26/2019	Covered and not covered code lists updated.
Revised	10/31/2019	Coverage aligned with LCD
Reviewed	08/26/2021	Minor changes
Updated	09/01/2022	Added to list of materials not covered
Updated	03/11/2024	Updated codes that are covered and not covered due to evolving evidence. Formatting changes, added hyperlinks to NCD and TMPPM, beginning and ending note sections updated to align with CMS requirements and business entity change.
Reviewed	08/12/2024	No changes
Updated	01/13/2025	Updated background information and treatable conditions for some covered products. Ending note section updated to align with business entity changes.

REFERENCES:

The following scientific references were utilized in the formulation of this medical policy. BSWHP will continue to review clinical evidence related to this policy and may modify it at a later date based upon the evolution of the published clinical evidence. Should additional scientific studies become available, and they are not included in the list, please forward the reference(s) to BSWHP so the information can be reviewed by the Medical Coverage Policy Committee (MCPC) and the Quality Improvement Committee (QIC) to determine if a modification of the policy is in order.

Reference for Platelet Rich Plasma
1. Ujash S, Simunovic N, Klein G, Fu F, Einhorn T, Schemitsch E, Ayeni O, Bhandari M. Efficacy of Autologous Platelet-Rich Plasma Use for Orthopaedic Indications: A Meta-Analysis. J Bone Joint Surg Am. 2012;94:298-307
2. Lee K, Wilson J, Rabago D, Baer G, Jacobson J, Borrero C. Musculoskeletal Applications of Platelet-Rich Plasma: Fad or Future? AJR 2011; 196:628–636
3. Hee HT, Majd ME, Holt RT, et al. Do autologous growth factors enhance transforaminal lumbar interbody fusion? Eur Spine J 2003;12:400-7
4. Yassibag-Berkman Z, Tuncer O, Subasioglu T, et al. Combined use of platelet-rich plasma and bone grafting with or without guided tissue regeneration in the treatment of anterior interproximal defects. J Periodontol. 2007;78(5):801-9
5. Carreon LY, Glassman ST, Anekstein Y, et al. Platelet gel (AGF) fails to increase fusion rates in instrumented posterolateral fusions. Spine 2005;30(9):E243-6
6. Buchwald D, Kaltschmidt C, Haardt H, et al. Autologous platelet gel fails to show beneficial effects on wound healing after saphenectomy in CABG patients. J Extra Corpor Technol. 2008;40(3):196-202

7. Driver VR, Hanft J, Fylling C, et al. A prospective, randomized controlled trial of autologous platelet-rich plasma gel for the treatment of diabetic ulcers. Ostomy Wound Manage 2006;52(6):68-87
8. Moraes VY, Lenza M, Tamaoki MJ, Faloppa F, Belloti JC. Platelet-rich therapies for musculoskeletal soft tissue injuries. Cochrane Database Syst Rev. 2013 Dec 23;(12):CD010071. doi: 10.1002/14651858.CD010071.pub2. Update in: Cochrane Database Syst Rev. 2014;(4):CD010071. PMID: 24363098.

Reference for Skin / Dermal Substitutes

1. Agency for Healthcare Research and Quality (AHRQ) Website. Technology Assessment. Negative pressure wound therapy devices. November 12, 2009.
2. Institute for Clinical Systems Improvement Website. Health Care Protocol: Pressure ulcer prevention and treatment protocol. January 2012. Available at: http://www.icsi.org
3. American Society of Plastic Surgeons (ASPS) [website]. Evidence-based Clinical Practice Guideline: Chronic Wounds of the Lower Extremity. May 21, 2007.
4. Weiss PR. Breast reconstruction after mastectomy. Am J Managed Care. 1997; 3(6):932-937.
5. Zion SM, Slezak JM, Sellers TA, et al. Re-operations after prophylactic mastectomy with or without implant reconstruction. Cancer. 2003; 98(10):2152-2160.
6. Centers for Medicare and Medicaid Services. National Coverage Determination for Breast Reconstruction Following Mastectomy. NCD #140.2. Effective January 1, 1997; revised October 3, 2003. Available at: http://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=64&ncdver=1&bc=AgAAQAAAAAAA&. Accessed on March 17, 2014.
7. Ibrahim AM, Ayeni OA, Hughes KB, et al. Acellular dermal matrices in breast surgery: A comprehensive review. Ann Plast Surg. 2013 Feb 12. [Epub ahead of print].
8. Cheng A, Saint-Cyr M. Comparison of different ADM materials in breast surgery. Clin Plast Surg. 2012;39(2):167-175.
9. Hayes Inc. Comparative Effectiveness Review. Acellular skin Substitutes for chronic foot Ulcers in adults with diabetes mellitus. Lansdale, PA: Hayes. May 2020, Updated April 2022.
10. Hayes Inc. Comparative Effectiveness Review. Cellular skin substitutes for chronic foot ulcers in adults with diabetes mellitus. Lansdale, PA: Hayes. March 2020.

Reference for Mesenchymal Stem Cells

1. Bonab MM, Alimoghaddam K, Talebian F, et al. Aging of mesenchymal stem cell in vitro. BMC Cell Biol. 2006; 7:14.
2. Buda R, Vannini, Cavallo, M, et al. One-step arthroscopic technique for the treatment of osteochondral lesions of the knee with bone-marrow-derived cells: three year results. Musculoskelet Surg. 2013; 97(2):145-151.
3. Filardo G, Madry H, Jelic M, et al. Mesenchymal stem cells for the treatment of cartilage lesions: from preclinical findings to clinical application in orthopaedics. Knee Surg Sports Traumatol Arthrosc. 2013 Jan 11. [Epub ahead of print].
4. American Academy of Orthopaedic Surgeons. Stem cells and orthopaedics. Last reviewed September 2007. Available at: http://orthoinfo.aaos.org/topic.cfm?topic=A00501. Accessed on July 3, 2013.
5. National Cancer Institute. Available at: http://www.cancer.gov. Accessed on July 3, 2013.
6. U.S National Institutes of Health. Stem Cell Information. January 15, 2013. Available at: http://stemcells.nih.gov/info/glossary.asp. Accessed on July 3, 2013.

Reference for Recombinant Human Bone Morphogenic Protein

1. Vaccaro AR, Lawrence JP, Patel T, et al. The safety and efficacy of OP-1 (rhBMP-7) as a replacement for iliac crest autograft in posterolateral lumbar arthrodesis: a long-term (>4 years) pivotal study. Spine (Phila Pa 1976). 2008; 33(26):2850-2862.
2. Vaccaro AR, Anderson DG, Patel T, et al. Comparison of OP-1 Putty (rhBMP-7) to iliac crest autograft for posterolateral lumbar arthrodesis: a minimum 2-year follow-up pilot study. Spine (Phila Pa 1976). 2005; 30(24):2709-2716.
3. Villavicencio AT, Burneikiene S, Nelson EL, et al. Safety of transforaminal lumbar interbody fusion and intervertebral recombinant human bone morphogenetic protein-2. J Neurosurg Spine. 2005; 3(6):436-443.
4. Williams BJ, Smith JS, Fu KM, et al.; Scoliosis Research Society Morbidity and Mortality Committee. Does bone morphogenetic protein increase the incidence of perioperative complications in spinal fusion? A comparison of 55,862

cases of spinal fusion with and without bone morphogenetic protein. Spine (Phila Pa 1976). 2011; 36(20):1685-1691.
5. Hayes Inc. Medical Technology Directory. Comparative effectiveness review of recombinant human bone morphogenetic protein (rhBMP) for use in spinal fusion. Lansdale, PA: January 2021.
6. Liu S, Wang Y, Liang Z, et al. Comparative clinical effectiveness and safety of bone morphogenetic protein versus autologous iliac crest bone graft in lumbar fusion: A meta-analysis and systematic review. Spine (Phila Pa 1976). 2020 Jun 15;45(12):E729- E741.

Reference for amniotic membrane transplant for ophthalmologic procedures
1. Connon, Che J., PhD, et al., "The Persistence of Transplanted Amniotic Membrane in Corneal Stroma," American Journal of Ophthalmology, Vol. 141, 2006, pp. 190-192.
2. Gomes, Jose A. P., "Amniotic Membrane use in Ophthalmology," Current Opinion in Ophthalmology, Vol. 16, Issue 4, August 2005, pp. 223-240.
3. Gris, Oscar, MD, et al., "Amniotic Membrane Implantation as a Therapeutic Contact Lens for the Treatment of Epithelial Disorders," Cornea, Vol. 21, No. 1, 2002, pp. 22-27.
4. Yildiz EH, Nurozler AB, Ozkan Aksoy N, Altiparmak UE, Onat M, Karaguzel H. Amniotic membrane transplantation: indications and results. Eur J Ophthalmol. 2008 Sep-Oct;18(5):685-90.
5. Shay E, Kheirkhah A, Liang L, Sheha H, Gregory DG, Tseng SC. Amniotic membrane transplantation as a new therapy for the acute ocular manifestations of Stevens-Johnson syndrome and toxic epidermal necrolysis. Surv Ophthalmol.2009 Nov-Dec;54(6):686-96. Epub 2009 Aug 21.
6. Müller M, Meltendorf C, Mirshahi A, Kohnen T. [Use of multilayer amniotic membrane as first therapy for penetrating corneal ulcers]. Klin Monatsbl Augenheilkd. 2009 Aug;226(8):640-4. Epub 2009 Aug 11.
7. Said DG, Nubile M, Alomar T, Hopkinson A, Gray T, Lowe J, Dua HS. Histologic features of transplanted amniotic membrane: implications for corneal wound healing. Ophthalmology. 2009 Jul;116(7):1287-95. Epub 2009 May 17.
8. American Academy of Orhtopaedic Surgeons, Position Statement: Use of Emerging Biologic Therapies. Position Statement 1187, 2017
9. Medicare HPMS Alert regarding Human Cell and Tissue Products, August 10, 2021
10. Pirouzian A. Management of pediatric corneal limbal dermoids. Clin Ophthalmol. 2013;7:607-614.

***Note**:*
Health Maintenance Organization (HMO) products are offered through Scott and White Health Plan dba Baylor Scott & White Health Plan, and Scott & White Care Plans dba Baylor Scott & White Care Plan. Insured PPO and EPO products are offered through Baylor Scott & White Insurance Company. Scott and White Health Plan dba Baylor Scott & White Health Plan serves as a third-party administrator for self-funded employer-sponsored plans. Baylor Scott & White Care Plan and Baylor Scott & White Insurance Company are wholly owned subsidiaries of Scott and White Health Plan. These companies are referred to collectively in this document as Baylor Scott & White Health Plan.

RightCare STAR Medicaid is offered through Scott and White Health Plan in the Central Texas Medicaid Rural Service Area (MRSA); FirstCare STAR is offered through SHA LLC dba FirstCare Health Plans (FirstCare) in the Lubbock and West MRSAs; and FirstCare CHIP is offered through FirstCare in the Lubbock Service Area.