

Skin Substitutes Grafts/Cellular and Tissue-Based Products (Injections and/or Applications)

Related Commercial Policy

Skin and Soft Tissue Substitutes

Policy Number: MMP105.13 Last Committee Approval Date: August 14, 2024 Effective Date: September 1, 2024

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Instructions for Use

Coverage Rationale

Amniotic and Placental Derived Product Injections and/or Applications for Musculoskeletal Indications, Non-Wound

Medicare does not have a National Coverage Determination (NCD) for amniotic and placental derived product injections and/or applications for musculoskeletal indications, non-wound. Local Coverage Determinations (LCDs)/Local Coverage Articles (LCAs) exist and compliance with these policies is required where applicable. For specific LCDs/LCAs, refer to the table for <u>Amniotic and Placental Derived Product Injections and/or Applications for Musculoskeletal Indications, Non-Wound</u>.

For coverage guidelines for states/territories with no LCDs/LCAs, refer to the UnitedHealthcare Commercial Medical Policy titled <u>Skin and Soft Tissue Substitutes</u>.

Skin Substitutes Grafts/Cellular and Tissue-Based Products (CTP)

Medicare does not have an NCD for skin substitutes grafts/cellular and tissue–based products. LCDs/LCAs exist for lower extremities and compliance with these policies is required where applicable. For specific LCDs/LCAs, refer to the table for Skin Substitutes Grafts/Cellular and Tissue-Based Products (CTP).

For coverage guidelines for states/territories with no LCDs/LCAs or for indications not listed in the existing LCDs/LCAs, refer to the UnitedHealthcare Commercial Medical Policy titled <u>Skin and Soft Tissue Substitutes</u>.

Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service; however, language may be included in the listing below to indicate if a code is non-covered. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

HCPCS Code	Description
A2001	InnovaMatrix AC, per sq cm
A2002	Mirragen Advanced Wound Matrix, per sq cm

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HCPCS Code	Description
A2004	XCelliStem, 1 mg
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
A2012	SUPRATHEL, per sq cm
A2013	Innovamatrix FS, per sq cm
A2014	Omeza Collagen Matrix, per 100 mg
A2015	Phoenix wound matrix, per sq cm
A2016	PermeaDerm B, per sq cm
A2017	PermeaDerm glove, each
A2018	PermeaDerm C, per sq cm
A2019	Kerecis Omega3 MariGen Shield, per sq cm
A2021	NeoMatriX, per sq cm
A4100	Skin substitute, FDA-cleared as a device, not otherwise specified
Q4100	Skin substitute, not otherwise specified
Q4110	PriMatrix, per sq cm
Q4111	GammaGraft, per sq cm
Q4112	Cymetra, injectable, 1 cc
Q4114	Integra flowable wound matrix, injectable, 1 cc
Q4115	AlloSkin, per sq cm
Q4117	HYALOMATRIX, per sq cm
Q4118	MatriStem micromatrix, 1 mg
Q4121	TheraSkin, per sq cm
Q4122	DermACELL, DermACELL AWM or DermACELL AWM Porous, per sq cm
Q4123	AlloSkin RT, per sq cm
Q4125	Arthroflex, per sq cm
Q4126	MemoDerm, DermaSpan, TranZgraft or InteguPly, per sq cm
Q4127	Talymed, per sq cm
Q4130	Strattice TM, per sq cm
Q4132	Grafix Core and GrafixPL Core, per sq cm
Q4133	Grafix PRIME, GrafixPL PRIME, Stravix and StravixPL, per sq cm
Q4134	HMatrix, per sq cm
Q4135	Mediskin, per sq cm
Q4136	E-Z Derm, per sq cm
Q4137	AmnioExcel, AmnioExcel Plus or BioDExcel, per sq cm
Q4138	BioDFence DryFlex, per sq cm
Q4139	AmnioMatrix or BioDMatrix, injectable, 1 cc
Q4140	BioDFence, per sq cm
Q4141	AlloSkin AC, per sq cm
Q4142	Xcm biologic tissue matrix, per sq cm
Q4143	Repriza, per sq cm

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HCPCS Code	Description
Q4145	EpiFix, injectable, 1 mg
Q4146	Tensix, per sq cm
Q4147	Architect, Architect PX, or Architect FX, extracellular matrix, per sq cm
Q4148	Neox Cord 1K, Neox Cord RT, or Clarix Cord 1K, per sq cm
Q4149	Excellagen, 0.1 cc
Q4150	AlloWrap DS or dry, per sq cm
Q4151	AmnioBand or Guardian, per sq cm
Q4152	DermaPure, per sq cm
Q4153	Dermavest and Plurivest, per sq cm
Q4154	Biovance, per sq cm
Q4155	Neox Flo or Clarix Flo 1 mg
Q4156	Neox 100 or Clarix 100, per sq cm
Q4157	Revitalon, per sq cm
Q4158	Kerecis Omega3, per sq cm
Q4159	Affinity, per sq cm
Q4160	Nushield, per sq cm
Q4161	Bio-connekt wound matrix, per sq cm
Q4162	WoundEx Flow, BioSkin Flow, 0.5 cc
Q4163	WoundEx, BioSkin, per sq cm
Q4164	Helicoll, per sq cm
Q4165	Keramatrix or Kerasorb, per sq cm
Q4166	Cytal, per sq cm
Q4167	Truskin, per sq cm
Q4168	Amnioband, 1 mg
Q4169	Artacent wound, per sq cm
Q4170	Cygnus, per sq cm
Q4171	Interfyl, 1 mg
Q4173	Palingen or palingen xplus, per sq cm
Q4174	Palingen or promatrx, 0.36 mg per 0.25 cc
Q4175	Miroderm, per sq cm
Q4176	Neopatch, per sq cm
Q4177	Floweramnioflo, 0.1 cc
Q4178	Floweramniopatch, per sq cm
Q4179	Flowerderm, per sq cm
Q4180	Revita, per sq cm
Q4181	Amnio wound, per sq cm
Q4182	Transcyte, per sq cm
Q4183	Surgigraft, per sq cm
Q4184	Cellesta or Cellesta Duo, per sq cm
Q4185	Cellesta Flowable Amnion (25 mg per cc); per 0.5
Q4186	Epifix, per sq cm
Q4187	Epicord, per sq cm
Q4188	AmnioArmor, per sq cm
Q4189	Artacent AC, 1 mg
Q4190	Artacent AC, per sq cm

HCPCS Code	Description
Q4191	Restorigin, per sq cm
Q4192	Restorigin, 1 cc
Q4193	Coll-e-Derm, per sq cm
Q4194	Novachor, per sq cm
Q4195	PuraPly, per sq cm
Q4196	PuraPly AM, per sq cm
Q4197	PuraPly XT, per sq cm
Q4198	Genesis Amniotic Membrane, per sq cm
Q4199	Cygnus matrix, per sq cm
Q4200	SkinTE, per sq cm
Q4201	Matrion, per sq cm
Q4202	Keroxx (2.5 g/cc), 1 cc
Q4203	Derma-Gide, per sq cm
Q4204	XWRAP, per sq cm
Q4205	Membrane graft or membrane wrap, per sq cm
Q4206	Fluid Flow or Fluid GF, 1 cc
Q4208	Novafix, per sq cm
Q4209	SurGraft, per sq cm
Q4211	Amnion Bio or AxoBioMembrane, per sq cm
Q4212	AlloGen, per cc
Q4213	Ascent, 0.5 mg
Q4214	Cellesta Cord, per sq cm
Q4215	Axolotl Ambient or Axolotl Cryo, 0.1 mg
Q4216	Artacent Cord, per sq cm
Q4217	WoundFix, BioWound, WoundFix Plus, BioWound Plus, WoundFix Xplus or BioWound Xplus, per sq cm
Q4218	SurgiCORD, per sq cm
Q4219	SurgiGRAFT-DUAL, per sq cm
Q4220	BellaCell HD or Surederm, per sq cm
Q4221	Amnio Wrap2, per sq cm
Q4222	ProgenaMatrix, per sq cm
Q4224	Human Health Factor 10 Amniotic Patch (HHF10-P), per sq cm
Q4225	AmnioBind or DermaBind TL, per sq cm
Q4226	MyOwn Skin, includes harvesting and preparation procedures, per sq cm
Q4227	AmnioCore TM, per sq cm
Q4229	Cogenex Amniotic Membrane, per sq cm
Q4230	Cogenex flowable amnion, per 0.5 cc
Q4231	Corplex p, per cc
Q4232	Corplex, per aq cm
Q4233	Surfactor or nudyn, per 0.5 cc
Q4234	Xcellerate, per sq cm
Q4235	AMNIOREPAIR or AltiPly, per sq cm
Q4236	carePATCH, per sq cm
Q4237	Cryo-Cord, per sq cm
Q4238	Derm-Maxx, per sq cm

HCPCS Code	Description
Q4239	Amnio-Maxx or Amnio-Maxx Lite
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
Q4245	Amniotext, per cc
Q4246	Coretext or protext, per cc
Q4247	Amniotext patch, per sq cm
Q4248	Dermacyte Amniotic Membrane Allograft, per sq cm
Q4249	AMNIPLY, for topical use only, per sq cm
Q4250	AmnioAmp-MP, per sq cm
Q4251	Vim, per sq cm
Q4252	Vendaje, per sq cm
Q4253	Zenith amniotic membrane, per sq cm
Q4254	Novafix DL, per sq cm
Q4255	REGUaRD, for topical use only, per sq cm
Q4256	MLG-Complete, per sq cm
Q4257	Relese, per sq cm
Q4258	Enverse, per sq cm
Q4259	Celera Dual Layer or Celera Dual Membrane, per sq cm
Q4260	Signature APatch, per sq cm
Q4261	TAG, per sq cm
Q4262	Dual Layer impax Membrane, per sq cm
Q4263	Surgraft TL, per sqcm
Q4264	Cocoon membrane, per sq cm
Q4265	NeoStim TL, per sq cm
Q4266	NeoStim Membrane, per sq cm
Q4267	NeoStim DL, per sq cm
Q4268	SurGraft FT, per sq cm
Q4269	SurGraft XT, per sq cm
Q4270	Complete SL, per sq cm
Q4271	Complete FT, per sq cm
Q4272	Esano A, per sq cm
Q4273	Esano AAA, per sq cm
Q4274	Esano AC, per sq cm
Q4275	Esano ACA, per sq cm
Q4276	ORION, per sq cm
Q4278	EPIEFFECT, per sq cm
Q4279	Vendaje AC, per sq cm
Q4280	Xcell Amnio Matrix, per sq cm
Q4281	Barrera SL or Barrera DL, per sq cm
Q4282	Cygnus Dual, per sq cm
Q4283	Biovance Tri-Layer or Biovance 3L, per sq cm
Q4284	DermaBind SL, per sq cm
Q4287	DermaBind DL, per sq cm
Q4288	DermaBind CH, per sq cm

HCPCS Code	Description
Q4289	RevoShield+ Amniotic Barrier, per sq cm
Q4290	Membrane Wrap-Hydro [™] , per sq cm
Q4291	Lamellas XT, per sq cm
Q4292	Lamellas, per sq cm
Q4293	Acesso DL, per sq cm
Q4294	Amnio Quad-Core, per sq cm
Q4295	Amnio Tri-Core Amniotic, per sq cm
Q4296	Rebound Matrix, per sq cm
Q4297	Emerge Matrix, per sq cm
Q4298	AmniCore Pro, per sq cm
Q4299	AmniCore Pro+, per sq cm
Q4300	Acesso TL, per sq cm
Q4301	Activate Matrix, per sq cm
Q4302	Complete ACA, per sq cm
Q4303	Complete AA, per sq cm
Q4304	GRAFIX PLUS, per sq cm
Q4310	Procenta, per 100 mg
Q4318	E-Graft, per sq cm
Q4326	WoundPlus, per sq cm
Q4331	Axolotl Graft, per sq cm
Q4332	Axolotl DualGraft, per sq cm

Definitions

Cellular and/or Tissue-Based Products (CTPs): CTPs accurately describes these products inclusive of both current and future technology. This terminology has been adopted and accepted by the wound care community, contractors, and other government agencies. The American Society for Testing and Materials (ASTM) updated its standard guide to define CTP nomenclature and they have also included synthetic products within the definition of a CTP. <u>A59518 - Response to</u> <u>Comments: Skin Substitute Grafts/Cellular and/or Tissue-Based Products for the Treatment of Diabetic Foot Ulcers and Venous Leg Ulcers</u>.

Centers for Medicare and Medicaid Services (CMS) Related Documents

After checking the table below and searching the <u>Medicare Coverage Database</u>, if no NCD, LCD, or LCA is found, refer to the criteria as noted in the <u>Coverage Rationale</u> section above.

NCD	LCD	LCA	Contractor Type	Contractor Name
Skin Substitutes G	irafts/Cellular and Tissue- B	ased Products (CTP)		
N/A	L36690 Wound Application of Cellular and/or Tissue Based Products (CTPs), Lower Extremities	A56696 Billing and Coding: Wound Application of Cellular and/or Tissue Based Products (CTPs), Lower Extremities	Part A and B MAC	CGS
	L36377 Application of Skin Substitute Grafts for Treatment of DFU and VLU of Lower Extremities	A57680 Billing and Coding: Application of Skin Substitute Grafts for Treatment of DFU and VLU of Lower Extremities	Part A and B MAC	First Coast

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NCD	LCD	LCA	Contractor Type	Contractor Name
Skin Substitutes G	irafts/Cellular and Tissue- I	Based Products (CTP)		
N/A	L35041 Application of Bioengineered Skin Substitutes to Lower Extremity Chronic Non- Healing Wounds.	A54117 Billing and Coding: Application of Bioengineered Skin Substitutes to Lower Extremity Chronic Non- Healing Wounds	Part A and B MAC	Novitas**
Amniotic and Place Wound	ental Derived Product Injec	tions and/or Applications fo	or Musculoskeletal li	ndications, Non-
N/A	L39575 Amniotic and Placental Derived Product Injections and/or Applications for Musculoskeletal Indications, Non-Wound	A59374 Billing and Coding: Amniotic and Placental- Derived Product Injections and/or Applications for Musculoskeletal Indications, Non-Wound	Part A and B MAC	CGS
	L39139 Amniotic and Placental-Derived Product Injections and/or Applications for Musculoskeletal Indications, Non-Wound	A58893 Billing and Coding: Amniotic and Placental- Derived Product Injections and/or Applications for Musculoskeletal Indications, Non-Wound	Part A and B MAC	NGS
	L39116 Amniotic and Placental-Derived Product Injections and/or Applications for Musculoskeletal Indications, Non-Wound	A58865 Billing and Coding: Amniotic and Placental- Derived Product Injections and/or Applications for Musculoskeletal Indications, Non-Wound	Part A and B MAC	Noridian
	L39118 Amniotic and Placental-Derived Product Injections and/or Applications for Musculoskeletal Indications, Non-Wound	A58867 Billing and Coding: Amniotic and Placental- Derived Product Injections and/or Applications for Musculoskeletal Indications, Non-Wound	Part A and B MAC	Noridian
	L39128 Amniotic and Placental-Derived Product Injections and/or Applications for Musculoskeletal Indications, Non-Wound	A58883 Billing and Coding: Amniotic and Placental- Derived Product Injections and/or Applications for Musculoskeletal Indications, Non-Wound	Part A and B MAC	Palmetto**
	L39624 Amniotic and Placental Derived Product Injections and/or Applications for Musculoskeletal Indications, Non-Wound	A59434 Billing and Coding: Amniotic and Placental- Derived Product Injections and/or Applications for Musculoskeletal Indications, Non-Wound	Part A and B MAC	WPS*

Medicare Administrative Contractor (MAC) With Corresponding States/Territories	
MAC Name (Abbreviation)	States/Territories
CGS Administrators, LLC (CGS)	КҮ, ОН
First Coast Service Options, Inc. (First Coast)	FL, PR, VI
National Government Services, Inc. (NGS)	CT, IL, ME, MA, MN, NH, NY, RI, VT, WI
Noridian Healthcare Solutions, LLC (Noridian)	AS, AK, AZ, CA, GU, HI, ID, MT, NV, ND, Northern Mariana Islands, OR, SD, UT, WA, WY
Novitas Solutions, Inc. (Novitas)	AR, CO, DC, DE, LA, MD, MS, NJ, NM, OK, PA, TX, VA**

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Medicare Administrative Contractor (MAC) With Corresponding States/Territories		
MAC Name (Abbreviation)	States/Territories	
Palmetto GBA (Palmetto)	AL, GA, NC, SC, TN, VA**, WV	
Wisconsin Physicians Service Insurance Corporation (WPS)*	IA, IN, KS, MI, MO, NE	

Notes

*Wisconsin Physicians Service Insurance Corporation: Contract Number 05901 applies only to WPS Legacy Mutual of Omaha MAC A Providers.

**For the state of Virginia: Part B services for the city of Alexandria and the counties of Arlington and Fairfax are excluded for the Palmetto GBA jurisdiction and included within the Novitas Solutions, Inc. jurisdiction.

Other(s)

Code of Federal Regulations, § 419.2 - Basis of payment

Policy History/Revision Information

Date	Summary of Changes
10/01/2024	Centers for Medicare & Medicaid (CMS) Related Documents
10/01/2024	 Added notation for the state of Virginia to indicate "Part B services for the city of Alexandria and
	the counties of Arlington and Fairfax are excluded for the Palmetto GBA jurisdiction and
	included within the Novitas Solutions, Inc. jurisdiction"
09/01/2024	Title Change/Template Update
00/01/2021	Previously titled <i>Wound Treatments</i>
	 Reformatted and reorganized policy; transferred content to new template
	Changed policy type classification from "Coverage Summary" to "Medical Policy"
	Added <i>Definitions</i> section
	Updated Instructions for Use
	Related Policies
	Added reference link to the UnitedHealthcare Commercial Medical Policy titled Skin and Soft
	Tissue Substitutes
	Removed reference link to the UnitedHealthcare Medicare Advantage Policy Guideline titled
	Porcine Skin and Gradient Pressure Dressings
	Coverage Rationale
	Removed content/language addressing:
	 Ablative laser treatment for wounds (CPT code 17999) (refer to the UnitedHealthcare
	Medicare Advantage Coverage Summary titled Omnibus Codes)
	 Electrical stimulation (ES) or electromagnetic therapy (refer to the <u>Medicare Coverage</u>
	Database and/or the UnitedHealthcare Medicare Advantage Coverage Summary titled
	Durable Medical Equipment (DME), Prosthetics, Orthotics (Non-Foot Orthotics), Nutritional
	 Therapy, and Medical Supplies Grid for applicable coverage guidelines) Non-contact normothermic wound therapy (refer to the Medicare Coverage Database for
	 Non-contact normothermic wound therapy (refer to the <u>Medicare Coverage Database</u> for applicable coverage guidelines)
	 Topical application of oxygen (HCPCS code E0446) (refer to the <u>Medicare Coverage</u>
	Database for applicable coverage guidelines)
	Amniotic and Placental Derived Product Injections and/or Applications for
	Musculoskeletal Indications, Non-Wound
	Added language to indicate:
	 Medicare does not have a NCD for amniotic and placental derived product injections and/or
	applications for musculoskeletal indications, non-wound
	 Local Coverage Determinations (LCDs)/Local Coverage Articles (LCAs) exist and
	compliance with these policies is required where applicable; for specific LCDs/LCAs, refer
	to the table [in the Centers for Medicare & Medicaid (CMS) Related Documents section of
	the policy]
	• For coverage guidelines for states/territories with no LCDs/LCAs, refer to the
	UnitedHealthcare Commercial Medical Policy titled Skin and Soft Tissue Substitutes

Date	Summary of Changes
	Skin Substitutes Grafts/Cellular and Tissue-Based Products (CTP)
	Modified service heading
	Revised language to indicate:
	 Medicare does not have a NCD for skin substitutes grafts/cellular and tissue-based
	 products LCDs/LCAs exist for lower extremities and compliance with these policies is required where
	applicable; for specific LCDs/LCAs, refer to the table [in the <i>Centers for Medicare</i> &
	Medicaid (CMS) Related Documents section of the policy]
	 For coverage guidelines for states/territories with no LCDs/LCAs or for indications not listed
	in the existing LCDs/LCAs, refer to the UnitedHealthcare Commercial Medical Policy titled
	Skin and Soft Tissue Substitutes
	Applicable Codes
	 Updated list of applicable CPT/HCPCS codes (previously located in the Coverage Rationale section):
	 Added A2001, A2002, A2004, A2005, A2006, A2007, A2008, A2009, A2010, A2011,
	A2012, A2013, A2014, A2015, A2016, A2017, A2018, A2019, A2021, A4100, Q4100,
	Q4110, Q4111, Q4112, Q4114, Q4115, Q4117, Q4118, Q4121, Q4122, Q4123, Q4125,
	Q4126, Q4127, Q4130, Q4132, Q4133, Q4134, Q4135, Q4136, Q4137, Q4138, Q4139,
	Q4140, Q4141, Q4142, Q4143, Q4145, Q4146, Q4147, Q4148, Q4149, Q4150, Q4151, Q4152, Q4153, Q4154, Q4155, Q4155, Q4157, Q4158, Q4159, Q4150, Q4151, Q4153, Q4154, Q4155, Q4
	Q4152, Q4153, Q4154, Q4155, Q4156, Q4157, Q4158, Q4159, Q4160, Q4161, Q4162, Q4163, Q4164, Q4165, Q4166, Q4167, Q4168, Q4169, Q4170, Q4171, Q4173, Q4174,
	Q4175, Q4176, Q4177, Q4178, Q4179, Q4180, Q4181, Q4182, Q4183, Q4184, Q4185,
	Q4186, Q4187, Q4188, Q4189, Q4190, Q4191, Q4192, Q4193, Q4194, Q4195, Q4196,
	Q4197, Q4198, Q4199, Q4200, Q4201, Q4202, Q4203, Q4204, Q4205, Q4206, Q4208,
	Q4209, Q4211, Q4212, Q4213, Q4214, Q4215, Q4216, Q4217, Q4218, Q4219, Q4220, Q4221, Q4222, Q4
	Q4221, Q4222, Q4224, Q4225, Q4226, Q4227, Q4229, Q4230, Q4231, Q4232, Q4233, Q4234, Q4235, Q4236, Q4237, Q4238, Q4239, Q4240, Q4241, Q4242, Q4245, Q4246,
	Q4247, Q4248, Q4249, Q4250, Q4251, Q4252, Q4253, Q4254, Q4255, Q4256, Q4257,
	Q4258, Q4259, Q4260, Q4261, Q4262, Q4263, Q4264, Q4265, Q4266, Q4267, Q4268,
	Q4269, Q4270, Q4271, Q4272, Q4273, Q4274, Q4275, Q4276, Q4278, Q4279, Q4280,
	Q4281, Q4282, Q4283, Q4284, Q4287, Q4288, Q4289, Q4290, Q4291, Q4292, Q4293,
	Q4294, Q4295, Q4296, Q4297, Q4298, Q4299, Q4300, Q4301, Q4302, Q4303, Q4304, Q4240, Q4240, Q4240, Q4240, Q4224, and Q4222
	Q4310, Q4318, Q4326, Q4331, and Q4332 Removed 17999 and E0446
	Centers for Medicare and Medicaid Services (CMS) Related Documents
	 Added list of:
	 Documents available in the <i>Medicare Coverage Database</i> for:
	 Amniotic and placental derived product injections and/or applications for
	musculoskeletal indications, non-wound
	 Skin substitutes grafts/cellular and tissue- based products (CTP)
	 Applicable Medicare Administrative Contractors (MACs) With Corresponding States/Territories
	 Added notation to indicate the Wisconsin Physicians Service Insurance Company (WPS)
	Contract Number 05901 applies only to WPS Legacy Mutual of Omaha MAC A Providers
	• Added reference link to the Code of Federal Regulations, § 419.2 - Basis of Payment
	Supporting Information
	Archived previous policy version MCS105.12

Instructions for Use

The Medicare Advantage Policy documents are generally used to support UnitedHealthcare coverage decisions. It is expected providers retain or have access to appropriate documentation when requested to support coverage. This document may be used as a guide to help determine applicable:

- Medical necessity coverage guidelines; including documentation requirements, and/or
- Medicare coding or billing requirements.

Medicare Advantage Policies are applicable to UnitedHealthcare Medicare Advantage Plans offered by UnitedHealthcare and its affiliates. This Policy is provided for informational purposes and does not constitute medical advice. It is intended to serve only as a general reference and is not intended to address every aspect of a clinical situation. Physicians and patients should not rely on this information in making health care decisions. Physicians and patients must exercise their independent clinical discretion and judgment in determining care. Treating physicians and healthcare providers are solely responsible for determining what care to provide to their patients. Members should always consult their physician before making any decisions about medical care.

Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The member specific benefit plan document identifies which services are covered, which are excluded, and which are subject to limitations. In the event of a conflict, the member specific benefit plan document supersedes this policy. For more information on a specific member's benefit coverage, please call the customer service number on the back of the member ID card or refer to the <u>Administrative Guide</u>.

Medicare Advantage Policies are developed as needed, are regularly reviewed, and updated, and are subject to change. They represent a portion of the resources used to support UnitedHealthcare coverage decision making. UnitedHealthcare may modify these Policies at any time by publishing a new version on this website. Medicare source materials used to develop these policies may include, but are not limited to, CMS statutes, regulations, National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), and manuals. This document is not a replacement for the Medicare source materials that outline Medicare coverage requirements. The information presented in this Policy is believed to be accurate and current as of the date of publication. Where there is a conflict between this document and Medicare source materials, the Medicare source materials apply. Medicare Advantage Policies are the property of UnitedHealthcare. Unauthorized copying, use, and distribution of this information are strictly prohibited.

UnitedHealthcare follows Medicare coverage guidelines found in statutes, regulations, NCDs, and LCDs to determine coverage. The clinical coverage criteria governing certain items or services referenced in this Medical Policy have not been fully established in applicable Medicare guidelines because there is an absence of any applicable Medicare statutes, regulations, NCDs, or LCDs setting forth coverage criteria and/or the applicable NCDs or LCDs include flexibility that explicitly allows for coverage in circumstances beyond the specific indications that are listed in an NCD or LCD. As a result, in these circumstances, UnitedHealthcare applies internal coverage criteria as referenced in this Medical Policy. The internal coverage criteria in this Medical Policy was developed through an evaluation of the current relevant clinical evidence in acceptable clinical literature and/or widely used treatment guidelines. UnitedHealthcare evaluated the evidence to determine whether it was of sufficient quality to support a finding that the items or services discussed in the policy might, under certain circumstances, be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.

Providers are responsible for submission of accurate claims. Medicare Advantage Policies are intended to ensure that coverage decisions are made accurately. UnitedHealthcare Medicare Advantage Policies use Current Procedural Terminology (CPT[®]), Centers for Medicare and Medicaid Services (CMS), or other coding guidelines. References to CPT[®] or other sources are for definitional purposes only and do not imply any right to reimbursement or guarantee claims payment.

For members in UnitedHealthcare Medicare Advantage plans where a delegate manages utilization management and prior authorization requirements, the delegate's requirements need to be followed.