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Medical Policy

Skin Substitutes in the Outpatient Setting

Policy Number: OCA 3.710
Version Number: 24
Version Effective Date: 01/01/22

Product Applicability	☒ **All Plan+ Products**
WellSense Health Plan ☒ NH Medicaid ☒ NH Medicare Advantage	**Boston Medical Center HealthNet Plan** ☒ MassHealth ACO ☒ MassHealth MCO ☒ Qualified Health Plans/ConnectorCare/Employer Choice Direct ☒ Senior Care Options

+ Note: Disclaimer and audit information is located at the end of this document.

Policy Summary

Certain tissue-engineered skin substitutes utilized in the outpatient setting for wound healing, per the Clinical Criteria section are considered **medically necessary** and do not require prior authorization. Other tissue-engineered skin substitutes utilized in the outpatient setting for wound healing, continuation of treatment after an inpatient admission, or certain products used for breast reconstruction, per the Clinical Criteria section, are considered medically necessary and do require prior authorization. The Plan's *Medically Necessary* medical policy, policy number OCA 3.14, includes the product-specific definitions of medically necessary treatment. An additional Plan prior authorization is not required for the use of skin substitutes utilized when the member is in an inpatient setting if the inpatient admission has already been authorized by the Plan.

Clinical Criteria

Tissue engineered skin substitutes are considered medically necessary when applicable criteria are met, as stated below in items A and B.

A. **Product-Specific Regulations and Standards:**

The skin substitute product meets ALL applicable state and federal regulations; meets ALL applicable standards established by the American Association of Tissue Banks for procuring and processing human cells, tissues, and cellular or tissue-based products (HCT/Ps); and meets ALL product-specific FDA requirements, as specified below in EITHER item 1 or item 2:

1. The product has received FDA premarket clearance/approval for the requested indication, if applicable for the product; OR

2. When the product may be marketed without FDA clearance/approval through section 361 of the Public Health Services Act, the manufacturer is compliant with regulations for FDA Human Cell and Tissue Establishment Registration and Listing (including reporting requirements and labeling guidelines) for the product; AND

B. **Criteria Based on Indication for Treatment and Prior Authorization Requirements:**

ONE (1) of the criteria must be met in items 1 through 3:

1. **Breast Reconstruction - Plan Prior Authorization is REQUIRED:** +

   The Plan considers ANY of the products in item a or item b to be medically necessary when used for a covered, medically necessary breast reconstruction+ procedure and Plan prior authorization is obtained:

   a. AlloDerm; OR

   b. Strattice; OR

   + Note: See the Plan's *Breast Reconstruction* medical policy, policy number OCA 3.43.

2. **Wound Healing**:

   ONE (1) of the criteria must be met in item 1 or item 2:

   a. **Wound Healing - Plan Prior Authorization is NOT Required**:

      The Plan considers ANY of the products in items (1) through (7) to be medically necessary and does NOT require prior authorization when used for wound healing:

      (1) Apligraf; OR

      (2) Dermagraft; OR

(3) Integra Bilayer Matrix Wound Dressing; OR

(4) Integra Dermal Regeneration Template; OR

(5) Integra Matrix; OR

(6) OASIS Burn Matrix; OR

(7) OASIS Wound Matrix; OR

b. **Wound Healing - Prior Authorization is REQUIRED:**

The Plan considers ANY of the products in items (1) through (3) to be medically necessary when used for wound healing and Plan prior authorization is obtained:

(1) Biobrane; OR

(2) OrCel; OR

(3) TransCyte; OR

3. **Continuation of Treatment for Wound Healing or Breast Reconstruction:**

Requests for continuation of treatment for wound healing or breast reconstruction in the outpatient setting that began in the inpatient setting must include written documentation submitted to the Plan of continued progress over the course of the inpatient and ongoing treatment. Prior authorization is REQUIRED.

Plan Medical Director Review Required: Plan Medical Director Review is required when the treating provider is requesting a skin substitute product NOT listed as a medically necessary product for the member's condition in the Clinical Criteria section. Applicable clinical information must be submitted to the Plan by the treating provider that includes the member's medical history, treatment to date for the member's condition, verification of the clinical validity and clinical utility of the skin substitute product for the requested indication (and an explanation why this product is preferred for the member's treatment when an alternative is documented in the Clinical Criteria section), and an individualized treatment plan for the member.

Limitations and Exclusions

A. **Contraindications for Using Skin Substitutes**:

Contraindications include ANY condition in items 1 through 4:

1. Active Charcot disease; OR

2. Evidence of infection in ulcer(s) targeted for treatment; OR

3. Exudate consistent with heavy bacterial contamination, or eschar or necrotic tissue that would interfere with graft take and healing; OR

4. Hypersensitivity or allergy to any components of the skin substitute.

B. **Skin Substitutes Considered Experimental and Investigational or NOT Medically Necessary**:

When a tissue-engineered skin substitute product is NOT considered medically necessary for the requested indication or the product is NOT listed in the Clinical Criteria section of this policy, the use of the skin substitute is considered experimental and investigational or NOT medically necessary until the clinical utility and clinical validity of the product can be consistently established for the requested indication.

The Plan's *Experimental and Investigational Treatment* medical policy, policy number OCA 3.12, includes the Plan's product-specific definitions of experimental or investigational treatment.

Variations

The Plan uses guidance from the Centers for Medicare & Medicaid Services (CMS) for medical necessity and coverage determinations for Senior Care Options (SCO) members and WellSense Medicare Advantage HMO members, including but not limited to national coverage determinations (NCDs), local coverage determinations (LCDs), local coverage articles (LCAs), and documentation included in Medicare manuals. At the time of the Plan's most recent policy review, NCD 270.5 includes medical necessity criteria for the use of porcine skin and gradient pressure dressings as an occlusive dressing for burns, donor sites of a homograft, and/or decubiti and other ulcers. Verify CMS guidelines in effect on the date of the prior authorization request for the tissue-engineered or biosynthetic product. When there is no guidance from CMS for the requested service, Plan-adopted clinical review criteria will be used to determine the medical necessity of the service.

Applicable Coding

The Plan uses and adopts up-to-date Current Procedural Terminology (CPT) codes from the American Medical Association (AMA), International Statistical Classification of Diseases and Related Health Problems, 10th revision (ICD-10) diagnosis codes developed by the World Health Organization and adapted in the United Stated by the National Center for Health Statistics (NCHS) of the Centers for Disease Control under the U.S. Department of Health and Human Services, and the Health Care Common Procedure Coding System (HCPCS) established and maintained by the Centers for Medicare & Medicaid Services (CMS). Since the AMA, NCHS, and CMS may update codes more frequently or at different intervals than Plan policy updates, the list of applicable codes included in this Plan policy is for informational purposes only, may not be all inclusive, and is subject to change without prior notification. Whether a code is listed in the Applicable Coding section of this Plan policy does not constitute or imply member coverage or provider reimbursement. Providers are responsible for

reporting all services using the most up-to-date industry-standard procedure and diagnosis codes as published by the AMA, NCHS, and CMS at the time of the service.

Providers are responsible for obtaining prior authorization for the services specified in the Clinical Criteria section and Limitations and Exclusions section, even if an applicable code appropriately describing the service that is the subject of this Plan policy is not included in this Applicable Coding section. See the Plan's *Breast Reconstruction* medical policy, policy number OCA 3.43, for applicable codes for breast reconstruction that are covered when medically necessary. Review the Plan's reimbursement policies for Plan billing guidelines. Coverage for services is subject to benefit eligibility under the member's benefit plan in effect at the time of the service. Member benefit documents are available at the following websites: www.bmchp.org for BMC HealthNet Plan members, www.SeniorsGetMore.org for Senior Care Options members, www.wellsense.org for WellSense New Hampshire Medicaid members, and www.WellSense.org/Medicare for WellSense Medicare Advantage HMO members.

HCPCS Codes	Codes Considered Medically Necessary for Breast Reconstruction WITH Prior Authorization
Q4116	AlloDerm, per sq cm
Q4130	Strattice TM, per sq cm

HCPCS Codes	Codes Considered Medically Necessary for Wound Healing WITH Prior Authorization
Q4100	Skin substitute, not otherwise specified Plan note: For Biobrane and OrCel only.
Q4182	Transcyte, per sq cm

HCPCS Codes	Codes Considered Medically Necessary for Wound Healing WITHOUT Prior Authorization
Q4101	Apligraf, per sq cm
Q4102	Oasis wound matrix, per sq cm
Q4103	Oasis burn matrix, per sq cm
Q4104	Integra bilayer matrix wound dressing (BMWD), per sq cm
Q4105	Integra dermal regeneration template (drt) or integra omnigraft dermal regeneration matrix, per sq cm
Q4106	Dermagraft, per sq cm
Q4108	Integra matrix, per sq cm
Q4124	OASIS ultra tri-layer wound matrix, per sq cm

HCPCS Code	Prior Authorization is Required to Determine if Code is Considered Medically Necessary or Experimental and Investigational for the Requested Indication
C1849	Skin substitute, synthetic, resorbable, per sq cm Plan note: Code is ONLY payable for the Senior Care Option products. The use of the specific type of synthetic skin substitute is considered medically necessary when applicable clinical review criteria are met in the Clinical Criteria section.

HCPCS Codes	Codes Considered Experimental and Investigational or NOT Medically Necessary for Wound Healing or Any Other Indication
A2001	Microlyte matrix, per square centimeter
A2002	Mirragen advanced wound matrix, per square centimeter
A2004	Xcellistem, per square centimeter
A2005	Microlyte matrix, per square centimeter
A2006	Novosorb synpath dermal matrix, per square centimeter
A2007	Restrata, per square centimeter
A2008	Theragenesis, per square centimeter
A2009	Symphony, per square centimeter
A2010	Apis, per square centimeter
Q4100	Skin substitute, not otherwise specified Plan note: This code may be used for products such as SurgiMend. Code considered experimental and investigational or NOT medically necessary when the skin substitute used for an indication other than breast reconstruction and/or for a product not listed as medically necessary for breast construction (e.g., SurgiMend).
Q4107	GRAFTJACKET, per sq cm
Q4110	PriMatrix, per sq cm
Q4111	GammaGraft, per sq cm
Q4112	Cymetra, injectable, 1 cc
Q4113	GRAFTJACKET XPRESS, injectable, 1 cc
Q4114	Integra flowable wound matrix, injectable, 1 cc
Q4115	AlloSkin, per sq cm
Q4116	AlloDerm, per sq cm Plan note: Code considered experimental and investigational or NOT medically necessary when product used for an indication other than breast reconstruction.
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 sqcm
Q4124	OASIS ultra tri-layer wound matrix, per sq cm
Q4125	Arthroflex, per sq cm
Q4126	MemoDerm, DermaSpan, TranZgraft or IntéguPly, per sq cm
Q4127	Talymed, per sq cm
Q4128	FlexHD AllopatchHD, or Matrix HD, per sq cm
Q4130	Strattice TM, per sq cm Plan note: Code considered experimental and investigational or NOT medically necessary when product used for an indication other than breast reconstruction.
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
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 square centimeter
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 centimeter
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 or Therion, 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
Q4183	Surgigraft, per sq cm
Q4184	Cellesta or Cellesta Duo, per sq cm
Q4185	Cellesta Flowable Amnion (25 mg per cc); per 0.5 cc
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
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	PurapPly XT, per sq cm
Q4198	Genesis Amniotic Membrane, per sq cm
Q4200	Skin TE, per sq cm
Q4201	Matrion, per sq cm
Q4202	Keroxx (2.5g/cc), 1cc
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 square centimeter
Q4209	Surgraft, per sq cm
Q4210	Axolotl Graft or Axolotl DualGraft, 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	Amniowrap2, per sq cm
Q4222	Progenamatrix, per sq cm
Q4226	MyOwn Skin, includes harvesting and preparation procedures, per sq cm
Q4227	AmnioCore™, 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 sq cm
Q4233	SurFactor or NuDyn, per 0.5 cc
Q4234	XCellerate, per sq cm
Q4235	AMNIOREPAIR or AltiPly, per sq cm
Q4237	Cryo-Cord, per sq cm
Q4238	Derm-Maxx, per sq cm
Q4239	Amnio-Maxx or Amnio-Maxx Lite, per sq cm
Q4240	CoreCyte, for topical use only, per 0.5 cc
Q4241	PolyCyte, for topical use only, per 0.5 cc
Q4242	AmnioCyte Plus, per 0.5 cc
Q4244	Procenta, per 200 mg
Q4245	AmnioText, per cc
Q4246	CoreText or ProText, per cc
Q4247	AmnioText patch, per sq cm
Q4248	Dermacyte Amniotic Membrane Allograft, per sq cm
Q4249	Amniply, for topical use only, per square centimeter

Q4250	AmnioAMP MP, per square centimeter
Q4251	Vim, per square centimeter
Q4252	Vendaje, per square centimeter
Q4253	Zenith amniotic membrane, per square centimeter
Q4254	Novafix DL, per square centimeter
Q4255	Reguard, for topical use only, per square centimeter

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Policy History

Original Approval Date	Original Effective Date* and Version Number	Policy Owner	Original Policy Approved by
Regulatory Approval: N/A Internal Approval: 02/24/09: Medical Policy, Criteria, and Technology Assessment Committee (MPCTAC) 02/24/09: Utilization Management Committee (UMC) 03/25/09: Quality Improvement Committee (QIC)	06/01/09 Version 1	Medical Policy Manager as Chair of MPCTAC	MPCTAC, QIC, and UMC

*Effective Date for the BMC HealthNet Plan Commercial Product: 01/01/12
*Effective Date for the WellSense New Hampshire Medicaid Product: 01/01/13

*Effective Date for the Senior Care Options Product: 01/01/16
*Effective Date for the WellSense Medicare Advantage HMO Product: 01/01/22

Policy Revisions History			
Review Date	**Summary of Revisions**	**Revision Effective Date and Version Number**	**Approved by**
02/01/10	Review for effective date 06/01/10. Updated references, coding, and criteria for Alloderm and Integra.	06/01/10 Version 2	02/22/10: MPCTAC 03/24/10: QIC
02/01/11	Added criteria for two new skin substitutes that are considered experimental and investigational: Hyalomatrix and MatriStem, added coverage criteria for Epicel that was previously considered investigational, updated references and coding.	Version 3	02/16/11: MPCTAC 03/23/11: QIC
01/01/12	Updated the definition for skin substitutes and the criteria for new skin substitutes that are investigational, removed criteria for skin substitutes that are covered without authorization, updated references and coding.	Version 4	01/18/12: MPCTAC 02/08/12: QIC
08/01/12	Off cycle review for Well Sense Health Plan, revised title to include reference to outpatient setting, revised Summary statement, reformatted Medical Policy Statement, revised Applicable Coding introductory paragraph, updated code list, revised Limitations.	Version 5	08/17/12: MPCTAC 09/06/12: QIC
01/01/13	Review for effective date 05/01/13. References updated and added, revised title and Summary section, reformatted Description of Item or Service section and Medical Policy Statement section, moved limitations from Medical Policy Statement section to Limitations section, and added skin substitute products to list in Limitations section. Referenced the following Plan policies: *Breast Reconstruction, Experimental and Investigational Treatment, Medically Necessary.* Examples of skin substitutes moved	05/01/13 Version 6	01/16/13: MPCTAC 02/21/13: QIC

Policy Revisions History			
	from Description of Item or Service section to Clinical Background Information section.		
08/14/13 and 08/15/13	Off cycle review for Well Sense Health Plan and merged policy format. Incorporate policy revisions dated 01/01/13 (as specified above) for the Well Sense Health Plan product; these policy revisions were approved by MPCTAC on 01/16/13 and QIC on 02/21/13 for applicable Plan products.	Version 7	08/14/13: MPCTAC (electronic vote) 08/15/13: QIC
01/01/14	Review for effective date 05/01/14. Added categories of skin substitutes in the Description of Item or Service section. New codes added as experimental and investigational in the Applicable Coding section after researching products. Updated references. Revised Limitations section without changing criteria. Referenced Plan's Breast Reconstruction policy (OCA: 3.43).	05/01/14 Version 8	01/15/14: MPCTAC 02/18/14: QIC
12/01/14	Review for effective date 03/01/15. Added the following HCPCS codes as experimental and investigational: Q4150 through Q4160.	03/01/15 Version 9	12/02/14: MPCTAC (electronic vote) 12/10/14: QIC
02/01/15	Review for effective date 06/01/15. Updated criteria in the Medical Policy Statement and Limitations sections. Revised Summary and References sections. Removed Commonwealth Care, Commonwealth Choice, and Employer Choice from the list of applicable products because the products are no longer available.	06/01/15 Version 10	02/18/15: MPCTAC 03/11/15: QIC
11/25/15	Review for effective date 01/01/16. Updated template with list of applicable products and corresponding notes. Updated references and language in the Applicable Coding section.	01/01/16 Version 11	11/18/15: MPCTAC 11/25/15: MPCTAC (electronic vote) 12/09/15: QIC
12/01/15	Review for effective date 04/01/16. Updated applicable code list.	04/01/16 Version 12	12/16/15: MPCTAC 01/13/16: QIC
11/01/16 and	Review for effective date 04/01/17.	01/01/17	11/16/16: MPCTAC

Policy Revisions History			
12/01/16	Administrative changes made to the Summary, Clinical Background Information, References, and Reference to Applicable Laws and Regulations sections. Criteria revised in the Limitations section. Updated the applicable code list.	Version 13	12/21/16: MPCTAC 01/11/17: QIC
12/01/17	Review for effective 01/01/18. Industry-wide updates to codes included in the Applicable Coding section.	01/01/18 Version 14	Not required for revisions associated with industry-wide code changes
11/01/17	Review for effective date 02/01/18. Revised criteria in the Medical Policy Statement and Limitations sections. Updated Definitions, Clinical Background Information, References, Other Applicable Policies, and Reference to Applicable Laws and Regulations sections. Plan notes revised in the Applicable Coding section.	02/01/18 Version 15	MPCTAC: 11/15/17
11/01/18	Review for effective date 02/01/19. Administrative changes made to the Description of Item or Service, Clinical Background Information, References, and Other Applicable Policies sections. Industry-wide code updates in the Applicable Coding section. Criteria updated in the Limitations section.	02/01/19 Version 16	11/21/18: MPCTAC
12/01/18	Review for effective date 02/01/19. Industry-wide updates made to the code list in the Applicable Coding section. Revisions related to these industry-wide code updates are included in the Limitations, Clinical Background Information, and References sections.	02/01/19 Version 17	12/19/18: MPCTAC
09/01/19	Review for effective date 10/01/19. Administrative change made to the Description of Item or Service, References, and Reference to Applicable Laws and Regulations sections. Industry-wide updates made to the code list in the Applicable Coding	10/01/19 Version 18	09/18/19: MPCTAC

Policy Revisions History			
	section.		
12/01/19	Review for effective date 01/01/20. Updated References section.	01/01/20 Version 19	12/18/19: MPCTAC
06/01/20	Review for effective 07/01/20. Industry-wide updates to codes included in the Applicable Coding section and related updates in the Limitations section.	07/01/20 Version 20	Not required for revisions associated with industry-wide code changes; 06/17/20: MPCTAC review
09/01/20	Review for effective date 10/01/20. Industry-wide code updates made to the Applicable Coding section. Related administrative changes made to the Limitations, Clinical Background Information, and References sections.	10/01/20 Version 21	09/16/20: MPCTAC
12/01/20	Review for effective date 01/01/21. Administrative changes made to the Description of Item or Service and References sections.	01/01/21 Version 22	12/16/20: MPCTAC
10/01/21	Review for effective date 11/01/21. Adopted new medical policy template; removed administrative sections, Medical Policy Statement section renamed Clinical Criteria section, and the Limitations section renamed Limitations and Exclusions section. Added WellSense Medicare Advantage HMO as an applicable product effective 01/01/22. Administrative changes made to the Policy Summary, Clinical Criteria, Limitations and Exclusions, Applicable Coding, and References sections. Industry-wide code updates made to the Applicable Coding section.	11/01/21 Version 23	10/20/21: MPCTAC
12/01/21	Review for effective date 01/01/22. Administrative changes made to Clinical Criteria, Limitations and Exclusions, Applicable Coding, and References sections. Industry-wide code updates made to the Applicable Coding section.	01/01/22 Version 24	12/15/21: MPCTAC

Next Review Date

12/01/22

Authorizing Entity

MPCTAC

Disclaimer Information: [+]

Medical Policies are the Plan's guidelines for determining the medical necessity of certain services or supplies for purposes of determining coverage. These Policies may also describe when a service or supply is considered experimental or investigational, or cosmetic. In making coverage decisions, the Plan uses these guidelines and other Plan Policies, as well as the Member's benefit document, and when appropriate, coordinates with the Member's health care Providers to consider the individual Member's health care needs.

Plan Policies are developed in accordance with applicable state and federal laws and regulations, and accrediting organization standards (including NCQA). Medical policies are also developed, as appropriate, with consideration of the medical necessity definitions in various Plan products, review of current literature, consultation with practicing Providers in the Plan's service area who are medical experts in the particular field, and adherence to FDA and other government agency policies. Applicable state or federal mandates, as well as the Member's benefit document, take precedence over these guidelines. Policies are reviewed and updated on an annual basis, or more frequently as needed. Treating providers are solely responsible for the medical advice and treatment of Members.

The use of this Policy is neither a guarantee of payment nor a final prediction of how a specific claim(s) will be adjudicated. Reimbursement is based on many factors, including member eligibility and benefits on the date of service; medical necessity; utilization management guidelines (when applicable); coordination of benefits; adherence with applicable Plan policies and procedures; clinical coding criteria; claim editing logic; and the applicable Plan – Provider agreement.

[+] *Plan* refers to Boston Medical Center Health Plan, Inc. and its affiliates and subsidiaries offering health coverage plans to enrolled members. The Plan operates in Massachusetts under the trade name Boston Medical Center HealthNet Plan and in other states under the trade name WellSense Health Plan.