EmblemHealth | ConnectiCare

Payment Integrity Administrative Policy:

Coding Guidelines: Device, Implant and Skin Substitutes (Facilities) (Commercial, Medicare & Medicaid)

EFFECTIVE DATE:	APPROVED BY
12/14/2023	**RPC (Reimbursement Policy Committee)**

Policy Statement:

This policy applies to facilities reporting on a UB04 claim form or its electronic equivalent. This policy applies to all products, physicians, and qualified health care professionals and outlines coding requirements for the billing of devices, implants, and/or skin substitutes along with their correlating procedures.

Applicable codes and further information regarding outpatient hospital services can be found in the CMS OCE HCPCS data file:

https://www.cms.gov/medicare/coding/outpatientcodeedit

This policy offers directives for inpatient and outpatient hospital services in the correct revenue coding based on guidelines set forth by the US Food and Drug Administration (FDA) classification of products as implants.

Reimbursement Information

An “implant” is defined by the FDA as “a device that is placed into a surgically or naturally formed cavity of the human body and is intended to remain there for a period of 30 days or more. In order to protect public health, FDA may determine that devices placed in subjects for shorter periods are also implants.”

Implants must remain in the patient’s body upon discharge from the inpatient stay or outpatient procedure. Implants may include but are not limited to: metal anchors artificial joints, pins, plates, radioactive seeds, metal screws, shunts, stents, and types of allografts.

A supply or instrument that is purposed to be removed or discarded during the same inpatient/ outpatient procedure or single episode of care is not considered an implant.

If an outpatient claim is submitted with a revenue code indicating the use of an implant, an appropriate HCPCS code that corresponds with an FDA definition of an implant must be reported as well. If the HCPCS code is not submitted or it does not meet the FDA definition of an implant, the claim line containing the implant revenue code will deny.

If an inpatient claim is submitted with a revenue code indicating the use of an implant, an appropriate HCPCS code that corresponds with an FDA definition of an implant must be reported as well. If the HCPCS code is not submitted or it does not meet the FDA definition of an implant, the claim line containing the implant revenue code will deny. Medical records may be required to ensure that the implant meets the FDA definition of an implant.

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Typically, payment for the costs of all internal and external components required for the function of a non-pass-through device is packaged into the APC/Inpatient payment for the associated procedure in which the device is used, unless specifically contracted otherwise. HCPCS codes and charges for all devices that are used to perform the procedures where such codes exist and are designated with a status indicator of "N" (for packaged payment) or "H" (for pass-through device payment) in the OPPS Addendum B that applies to the date of service. Only HCPCS codes with status code "H" are eligible for separate reimbursement for Medicare or contracts that follow Medicare payment methodology.

Use of C1889

For procedure codes that require the use of devices that are not described by a specific HCPCS code, hospitals should report HCPCS code C1889 (Implantable/insertable device, not otherwise classified) and charges for all devices that are used to perform the procedures.

Such devices must:

- Have received FDA marketing authorization, have received an FDA investigational device exemption (IDE) and have been classified as a Category B device by FDA in accordance with 405.203 through 405.207 and 405.211 through 405.215, or meets another appropriate FDA exemption from premarket review;
- Be an integral part of the service furnished;
- Be used for one patient only;
- Come in contact with human tissue;
- Be surgically implanted or inserted (either permanently or temporarily); and
- Not be either of the following:

(a) Equipment, an instrument, apparatus, implement, or item of the type for which depreciation and financing expenses are recovered as depreciable assets.

(b) A material or supply furnished to a service (for example, a suture, customized surgical kit, scalpel, or clip, other than a radiological site marker).

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Below are examples of supplies, instruments and miscellaneous items that will not be additionally reimbursed outside of the global fee:

Advanced Hemostats & Sealants	Synthetic Sealants	Topical Absorbable Hemostats (Tah) & Topical Thrombins	Instruments & Miscellaneous
Surgiflo	Duraseal	Surgicel	Bone Morphogenetic Proteins (BMP)
Evicel	Bioglue	Instant Surgifoam	Bone Putty
Floseal	Progel	Arista	Endoscopes/surgical equipment
Tisseel	Coseal	Avitene	Catheters/cannulas
Seprafilm	Omnex	Gelfoam Plus	Staples
		Evithrom	Clips

Device and Implant Dependent Services:

The use of a device , implant, or multiple devices or implants, is necessary to the execution of many procedures. When reporting a procedure that requires the utilization of a device or implant, the procedure must be billed in conjunction with the device or implant with the same date of service on the same claim. If this fails to occur, the claim will be returned to the provider.

Devices and/or implants that are considered pass-through devices, OCE Status Indicator H, must be billed with a procedure with OCE Status J1, S, or T on the same claim with the same date of service or the claim will deny.

A code on this list does not constitute coverage or payment.

Device Dependent Procedures:									
0200T	0221T	0234T	0236T	0237T	0238T	0253T	0268T	0275T	0308T
0335T	0404T	0408T	0409T	0410T	0414T	0421T	0424T	0425T	0426T
0427T	0431T	0442T	0449T	0505T	0511T	0515T	0516T	0517T	0519T
0520T	0524T	0525T	0526T	0527T	0571T	0572T	0583T	0587T	0594T
0600T	0601T	0614T	0616T	0617T	0618T	0619T	0620T	0627T	0629T

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Device Dependent Procedures:									
0644T	0647T	0651T	0652T	0653T	0671T	0707T	0744T	0775T	0793T
0797T	0803T	0809T	10035	11970	19281	19283	19285	19287	19296
20690	20692	20696	20900	20983	21122	21150	21195	21243	21244
21245	21256	21267	21346	21347	21365	21422	21450	21452	21453
21461	21462	21470	21742	21812	21813	22551	22554	22612	22630
22633	22856	22867	22869	22899	23395	23470	23472	23473	23485
23491	23515	23552	23585	23615	23616	23630	23680	24126	24340
24344	24360	24361	24362	24363	24365	24366	24370	24371	24400
24420	24430	24435	24498	24515	24516	24545	24546	24575	24579
24586	24587	24615	24635	24666	24685	25126	25332	25350	25390
25391	25400	25405	25415	25420	25426	25441	25442	25443	25444
25445	25446	25515	25526	25545	25574	25575	25607	25608	25609
25652	25800	25805	25810	25820	25825	26530	26531	26536	26541
26568	26820	26843	26844	27110	27130	27279	27357	27381	27396
27403	27412	27415	27427	27428	27429	27430	27438	27440	27442
27443	27446	27447	27477	27509	27637	27647	27652	27654	27656
27695	27696	27698	27700	27702	27705	27709	27720	27722	27726
27745	27756	27758	27759	27792	27814	27822	27823	27826	27827
27828	27829	27832	27870	27871	28102	28103	28202	28210	28261
28262	28291	28297	28298	28299	28300	28302	28305	28309	28310
28320	28322	28415	28420	28436	28445	28446	28485	28555	28585
28615	28705	28715	28725	28730	28735	28737	28740	28750	29855
29856	29867	29885	29888	29889	29899	29907	30468	30469	31636
31647	31660	31661	32994	33206	33207	33208	33212	33213	33214
33216	33217	33220	33221	33224	33226	33227	33228	33229	33230
33231	33233	33234	33235	33240	33249	33262	33263	33264	33270
33271	33274	33275	33285	33289	33900	33901	33902	33903	33999

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Device Dependent Procedures:									
34421	35881	36253	36254	36583	36835	36836	36837	36903	36904
36906	37183	37184	37187	37191	37192	37211	37221	37224	37225
37226	37227	37228	37229	37230	37231	37236	37238	37241	37242
41512	42900	43210	43212	43229	43240	43266	43284	43497	43647
43770	44370	44390	44402	44405	45327	45347	45389	46707	47383
47538	47539	47540	47553	47556	50570	50593	51715	51992	52327
53440	53444	53445	53447	53451	53452	54400	54401	54405	54410
54411	54416	54417	54660	55873	55874	55876	57288	58565	59072
61626	61885	61886	61888	62350	62360	62361	62362	63075	63610
63650	63655	63663	63664	63685	63741	63744	64448	64553	64555
64561	64568	64569	64575	64580	64581	64582	64583	64590	64628
64716	64802	64858	64865	64886	64891	64892	64893	64897	64910
64912	65770	65779	65781	66175	66179	66180	66183	66989	66991
69705	69706	69714	69716	69717	69719	69729	69730	69930	75741
75831	75870	75898	92920	92924	92928	92933	92937	92943	92986
92987	93580	93581	93582	93590	93591	93600	93602	93603	93619
93650	93653	93654	93656	95938	95961	C9600	C9602	C9604	C9607
C9728	C9739	C9740	C9764	C9765	C9766	C9767	C9769	C9771	C9772
C9773	C9774	C9775	C9777	C9778	C9780	C9781	C9782	C9783	

A code on this list does not constitute coverage or payment.

Device Dependent Devices:									
A4648	C1052	C1062	C1713	C1714	C1715	C1721	C1722	C1724	C1725
C1726	C1727	C1728	C1729	C1730	C1731	C1732	C1733	C1734	C1747
C1748	C1749	C1750	C1751	C1752	C1753	C1754	C1755	C1756	C1757
C1758	C1759	C1760	C1761	C1762	C1763	C1764	C1765	C1766	C1767
C1768	C1769	C1770	C1771	C1772	C1773	C1776	C1777	C1778	C1779

Device Dependent Devices:									
C1780	C1781	C1782	C1783	C1784	C1785	C1786	C1787	C1788	C1789
C1813	C1814	C1815	C1816	C1817	C1818	C1819	C1820	C1821	C1822
C1823	C1824	C1825	C1826	C1827	C1830	C1831	C1833	C1839	C1840
C1874	C1875	C1876	C1877	C1878	C1880	C1881	C1882	C1883	C1884
C1885	C1886	C1887	C1888	C1889	C1891	C1892	C1893	C1894	C1895
C1896	C1897	C1898	C1899	C1900	C1982	C2596	C2613	C2614	C2615
C2617	C2618	C2619	C2620	C2621	C2622	C2623	C2624	C2625	C2626
C2627	C2628	C2629	C2630	C2631	L8600	L8603	L8604	L8605	L8606
L8607	L8609	L8610	L8612	L8613	L8614	L8630	L8631	L8641	L8642
L8658	L8659	L8670	L8679	L8682	L8690	L8699	L9900	V2630	V2631
V2632									

Examples of HCPCS Not Meeting the FDA Definition of an Implant:									
C1724	C1725	C1726	C1727	C1728	C1729	C1730	C1731	C1732	C1733
C1753	C1754	C1755	C1756	C1757	C1758	C1759	C1765	C1766	C1769
C1773	C1782	C1819	C1884	C1885	C1887	C1892	C1893	C1894	C2614
C2615	C2618	C2628	C2629	C2630					

Absorbable, Liquid and other closure methods

Absorbable material and liquids, such as synthetic sealants, advanced hemostats and sealants, bone morphogenetic protein, topical absorbable hemostats and topical thrombins, bone putty or cement, staples, and clips, are not separately payable. They are considered part of the inpatient or outpatient hospital service. Any liquids or other materials that are absorbed by surrounding tissue are non-reimbursable, as they are considered part of the implant procedure.

Application of Skin Substitutes/Grafts:

Autografts are not eligible for separate reimbursement as the cost for the harvest and preparation are included in the procedure charge.

A skin substitute application or replacement procedure is required to be billed on the same claim with the same date of service as the coinciding skin substitute product. Skin substitutes are billed under revenue code 636.

CMS categorizes skin substitutes as low- and high-cost products and can be found in the OCE HCPCS data file. We follow CMS and package payment for skin substitute products that don't qualify for hospital OPPS passthrough status into the OPPS payment for the associated skin substitute application procedure. This policy also applies to our ASC or other ambulatory payment methodology.

Skin Substitute Low Procedures:

Skin substitute application or replacement procedures considered low cost must be reported with a skin substitute product considered low cost on the same date of service and on the same claim, or the claim will be denied.

CPT Code	Description
C5271	Application of low-cost skin substitute graft to trunk, arms, legs, total wound surface area up to 100 sq cm; first 25 sq cm or less wound surface area
C5272	Application of low-cost skin substitute graft to trunk, arms, legs, total wound surface area up to 100 sq cm; each additional 25 sq cm wound surface area, or part thereof (list separately in addition to code for primary procedure)
C5273	Application of low-cost skin substitute graft to trunk, arms, legs, total wound surface area greater than or equal to 100 sq cm; first 100 sq cm wound surface area, or 1% of body area of infants and children
C5274	Application of low-cost skin substitute graft to trunk, arms, legs, total wound surface area greater than or equal to 100 sq cm; each additional 100 sq cm wound surface area, or part thereof, or each additional 1% of body area of infants and children, or part thereof (list separately in addition to code for primary procedure)
C5275	Application of low-cost skin substitute graft to face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits, total wound surface area up to 100 sq cm; first 25 sq cm or less wound surface area
C5276	Application of low-cost skin substitute graft to face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits, total wound surface area up to 100 sq cm; each additional 25 sq cm wound surface area, or part thereof (list separately in addition to code for primary procedure)

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CPT Code	Description
C5277	Application of low-cost skin substitute graft to face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits, total wound surface area greater than or equal to 100 sq cm; first 100 sq cm wound surface area, or 1% of body area of infants and children
C5278	Application of low-cost skin substitute graft to face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits, total wound surface area greater than or equal to 100 sq cm; each additional 100 sq cm wound surface area, or part thereof, or each additional 1% of body area of infants and children, or part thereof (list separately in addition to code for primary procedure)

Skin Substitute Low Products:									
A4100	Q4100	Q4102	Q4111	Q4115	Q4117	Q4124	Q4135	Q4136	Q4165
Q4166	Q4204	Q4214	Q4216	Q4218	Q4220	Q4221	Q4224	Q4225	Q4236
Q4247	Q4250	Q4251	Q4252	Q4253	Q4255	Q4256	Q4257	Q4259	Q4260
Q4261	Q4262	Q4263	Q4264	Q4265	Q4266	Q4267	Q4268	Q4269	Q4270
Q4271	Q4272	Q4273	Q4274	Q4275	Q4276	Q4277	Q4278	Q4280	Q4281
Q4282	Q4283	Q4284							

Skin Substitute High Procedures:

Skin substitute application or replacement procedures considered high cost must be reported with a skin substitute product considered high cost on the same date of service and on the same claim, or the claim will be denied.

CPT Code	Description
15271	Application of skin substitute graft to trunk, arms, legs, total wound surface area up to 100 sq cm; first 25 sq cm or less wound surface area
15272	Application of skin substitute graft to trunk, arms, legs, total wound surface area up to 100 sq cm; each additional 25 sq cm wound surface area, or part thereof (List separately in addition to code for primary procedure)
15273	Application of skin substitute graft to trunk, arms, legs, total wound surface area greater than or equal to 100 sq cm; first 100 sq cm wound surface area, or 1% of body area of infants and children

CPT Code	Description
15274	Application of skin substitute graft to trunk, arms, legs, total wound surface area greater than or equal to 100 sq cm; each additional 100 sq cm wound surface area, or part thereof, or each additional 1% of body area of infants and children, or part thereof (List separately in addition to code for primary procedure)
15275	Application of skin substitute graft to face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits, total wound surface area up to 100 sq cm; first 25 sq cm or less wound surface area
15276	Application of skin substitute graft to face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits, total wound surface area up to 100 sq cm; each additional 25 sq cm wound surface area, or part thereof (List separately in addition to code for primary procedure)
15277	Application of skin substitute graft to face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits, total wound surface area greater than or equal to 100 sq cm; first 100 sq cm wound surface area, or 1% of body area of infants and children
15278	Application of skin substitute graft to face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits, total wound surface area greater than or equal to 100 sq cm; each additional 100 sq cm wound surface area, or part thereof, or each additional 1% of body area of infants and children, or part thereof (List separately in addition to code for primary procedure)
15777	Implantation of biologic implant (eg, acellular dermal matrix) for soft tissue reinforcement (ie, breast, trunk) (List separately in addition to code for primary procedure)

Skin Substitute High Products:									
A2001	A2002	A2005	A2006	A2007	A2008	A2009	A2010	A2011	A2012
A2013	A2015	A2016	A2017	A2018	A2019	A2020	A2021	C9363	Q4101
Q4103	Q4104	Q4105	Q4106	Q4107	Q4108	Q4110	Q4116	Q4121	Q4122
Q4123	Q4126	Q4127	Q4128	Q4132	Q4133	Q4134	Q4137	Q4138	Q4140
Q4141	Q4143	Q4146	Q4147	Q4148	Q4150	Q4151	Q4152	Q4153	Q4154
Q4156	Q4157	Q4158	Q4159	Q4160	Q4161	Q4163	Q4164	Q4167	Q4169
Q4170	Q4173	Q4175	Q4176	Q4178	Q4179	Q4180	Q4181	Q4182	Q4183
Q4184	Q4186	Q4187	Q4188	Q4190	Q4191	Q4193	Q4194	Q4195	Q4196
Q4197	Q4198	Q4199	Q4200	Q4201	Q4203	Q4205	Q4208	Q4209	Q4210

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Q4211	Q4217	Q4219	Q4222	Q4226	Q4227	Q4229	Q4232	Q4234	Q4235
Q4237	Q4238	Q4239	Q4248	Q4249	Q4254	Q4258			

Additional Reimbursement Information:

- Billed charges for Revenue Code 278 may require a vendor's invoice that indicates the implants used corresponds to the services rendered.
- If units are missing, do not match, or are not clearly indicated on the vendor invoice, revenue code 278 will be denied

- If implants are purchased by the provider in bulk, the units that apply to the claim billed must be noted on the invoice or the revenue code 278 will be denied.
- Provider storage and/or delivery costs are not reimbursable.
- Patients should not be responsible for any items or services encompassed under the surgical rate charge.
- EmblemHealth/ ConnectiCare will not reimburse implants and/or supplies in the following situations that constitute waste:
  - If items are opened by mistake;
  - If the surgeon decides not to use an item;
  - If there are technical difficulties or equipment failure;
  - If the surgery case is cancelled;
  - If implants or supplies are considered contaminated;
  - If large quantities of implants or supplies are purchased when smaller packaging would be appropriate; and/or
  - If items are opened and prepared for a service but they are not used or implanted into the patient.

References:

- Center for Medicare and Medicaid Services (CMS), Manual System and other CMS publications and services
- Center for Medicare and Medicaid Services (CMS) Integrated Outpatient Code Edit (IOCE)
- Center for Medicare and Medicaid Services (CMS) Hospital Outpatient Prospective Payment System (OPPS)
- Code of Federal Register U.S Food and Drug Administration
- https://www.fda.gov/medical-devices/products-and-medical-procedures/implants-and-prosthetics
- https://www.fda.gov/medical-devices/investigational-device-exemption-ide/ide-definitions-and-acronyms
- Clinical and Applied Thrombosis/Hemostasis 16(5) 497-514 https://journals.sagepub.com/doi/pdf/10.1177/1076029610363589

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Revision History

Company(ies)	DATE	REVISION
EmblemHealth/ ConnectiCare	1/16/2024	• Updated Reimbursement Information section to clarify that pass-through device payment packaging does not apply to providers that are **specifically contracted otherwise** • Updated Reimbursement Information section regarding separate reimbursement for HCPCS codes with status code "H" to include **contracts that follow Medicare methodology**
EmblemHealth/ ConnectiCare	8/23/2023	• Policy created for clarification purposes