

Amniotic Membrane and Amniotic Fluid

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Disclaimer

Highmark Health Options medical policy is intended to serve only as a general reference resource regarding coverage for the services described. This policy does not constitute medical advice and is not intended to govern or otherwise influence medical decisions.

POLICY STATEMENT

Human amniotic membrane (HAM) forms the innermost layer of the placenta and is harvested from the time of caesarean section. It is cleaned, sterilized and cryo-preserved or dehydrated and can be utilized to facilitate wound healing in diabetic and venous ulcers or sutured onto ocular surfaces.

Amniotic fluid contains a concentration of growth factors and nutrients that promote healing in soft-tissue repair of bone, tendon and cartilage, as well as reducing inflammation and pain, in conditions such as osteoarthritis and plantar fasciitis.

DEFINITIONS

Highmark Health Options (HHO) – Managed care organization serving vulnerable populations that have complex needs and qualify for Medicaid. Highmark Health Options members include individuals and families with low income, expecting mothers, children, and people with disabilities. Members pay nothing to very little for their health coverage. Highmark Health Options currently serves Delaware Medicaid: Delaware Healthy Children Program (DHCP) and Diamond State Health Plan and Health Plan Plus members.

POLICY POSITION

Treatment of nonhealing* diabetic lower-extremity ulcers using ANY of the following HAM products may be considered medically necessary:

- AmnioBand® Membrane; or
- Biovance®; or
- Epifix®; or
- Grafix™.

Note: Nonhealing is defined as less than a 20% decrease in wound area with standard wound care for at least two (2) weeks.

All other HAM products for the treatment of nonhealing diabetic lower-extremity ulcers not listed above are considered experimental/investigational and, therefore, noncovered because the safety and/or effectiveness of this service cannot be established by the available published peer-reviewed literature.

Treatment of non-healing venous stasis ulcers using Graftax may be considered medically necessary when BOTH of the following criteria are met:

- Partial- or full-thickness venous stasis ulcer of greater than four weeks duration for which standard wound therapy has failed
- Treated lower extremity has adequate blood supply as evidenced by either the presence of a palpable pedal pulse or an ankle-brachial index (ABI) of greater than or equal to 0.70

When the above medical necessity criteria are met, the following conditions of coverage apply:

- Treatment is limited to one initial application
- Additional applications at a minimum of one week intervals, for up to a maximum of four in 12 weeks are considered medically necessary when evidence of wound healing is present (e.g., signs of epithelialization and reduction in ulcer size)

Additional applications beyond 12 weeks are considered not medically necessary regardless of wound status.

All other HAM products for the treatment of venous stasis ulcers not listed above are considered experimental/investigational and, therefore, noncovered because the safety and/or effectiveness of this service cannot be established by the available published peer-reviewed literature.

Sutured human amniotic membrane HAM grafts may be considered medically necessary for the treatment of ANY of the following ophthalmic indications:

- Neurotrophic keratitis; or
- Corneal ulcers and melts; or
- Pterygium repair; or
- Stevens-Johnson syndrome; or
- Persistent epithelial defects.*

Note: A persistent epithelial defect is one that failed to close completely after five (5) days of conservative treatment or has failed to demonstrate a decrease in size after two (2) days of conservative treatment. Conservative treatment is defined as use of topical lubricants and/or topical antibiotics and/or therapeutic contact lens and/or patching.

Sutured HAM grafts are considered experimental/investigational and, therefore, noncovered for the treatment of all other ophthalmic conditions because the safety and/or effectiveness of this service cannot be established by the available published peer-reviewed literature.

Human amniotic membrane (HAM) grafts without suture (Prokera®, AmbioDisk™) may be considered medically necessary for the treatment of the following ophthalmic indications:

- Neurotrophic keratitis with ocular surface damage and inflammation that does not respond to conservative therapy; or
- Corneal ulcers and melts that do not respond to initial conservative therapy; or
- Corneal perforation when there is active inflammation after corneal transplant requiring adjunctive treatment; or

- Bullous keratopathy as a palliative measure in patients who are not candidates for curative treatment (e.g., endothelial or penetrating keratoplasty); or
- Partial limbal stem cell deficiency with extensive diseased tissue where selective removal alone is not sufficient; or
- Moderate or severe Stevens-Johnson syndrome; or
- Persistent epithelial defects that do not respond within 2 days to conservative therapy; or
- Severe dry eye (DEWS 3 or 4) with ocular surface damage and inflammation that remains symptomatic after Steps 1, 2, and 3 of the dry eye disease management algorithm; or
- Moderate or severe acute ocular chemical burn.

Noncovered Services

HAM grafts without suture are considered experimental/investigational and, therefore, noncovered for the treatment of all other ophthalmic conditions because the safety and/or effectiveness of this service cannot be established by the available published peer-reviewed literature.

Injection of micronized or particulated human amniotic membrane is considered experimental/investigational and, therefore, noncovered for all indications because the safety and/or effectiveness of this service cannot be established by the available published peer-reviewed literature.

Injection of human amniotic fluid is considered experimental/investigational and, therefore, noncovered for all indications because the safety and/or effectiveness of this service cannot be established by the available published peer-reviewed literature.

Covered Procedure Codes

65778	Placement Of Amniotic Membrane On The Ocular Surface; Without Sutures.
65779	Placement Of Amniotic Membrane On The Ocular Surface; Single Layer, Sutured.
Q4100	Skin Substitute, Not Otherwise Specified.
Q4132	Graphix Core And Grapfixpl Core, Per Square Centimeter.
Q4133	Grafix Prime, Grafixpl Prime, Stravix And Stravixpl, Per Square Centimeter.
Q4137	Amnioexcel, Amnioexcel Plus Or Biodexcel, Per Square Centimeter.
Q4138	Biodfence Dryfkex, Per Square Centimeter.
Q4139	Amniomatrix Or Biomatrix, Injectable, 1 Cc.

Q4140	Biodfence, Per Square Centimeter.
Q4145	Epifix, Injectable, 1 Mg.
Q4148	Neox Cord 1k, Neox Cord Rt, Or Clarix Cord 1k, Per Square Centimeter.
Q4150	Allowrap Ds Or Dry, Per Square Centimeter.
Q4151	Amnioband Or Guardian, Per Square Centimeter.
Q4153	Dermavest And Plurivest, Per Square Centimeter.
Q4154	Biovance, Per Square Centimeter.
Q4155	Neoxflo Or Clarixflo, 1 Mg.
Q4156	Neox 100 Or Clarix 100, Per Square Centimeter.
Q4157	Revitalon, Per Square Centimeter.
Q4159	Affinity, Per Square Centimeter.
Q4160	Nushield, Per Square Centimeter.
Q4162	Woundex Flow, Bioskin Flow, 0.5 Cc.
Q4163	Woundex, Bioskin, Per Square Centimeter.
Q4168	Amnioband, 1 Mg.
Q4169	Artacent Wound, Per Square Centimeter.
Q4170	Cygnus, Per Square Centimeter.
Q4171	Interfyl, 1 Mg
Q4173	Palingen Or Palingen Xplus, Per Square Centimeter.
Q4174	Palingen Or Promatrx, 0.36 Mg Per 0.25 Cc.
Q4176	Neopatch Or Therion, Per Square Centimeter.
Q4177	Floweramnioflo, 0.1 Cc.
Q4178	Floweramniopatch, Per Square Centimeter.
Q4180	Revita, Per Square Centimeter.
Q4183	Surgigraft, Per Square Centimeter.
Q4184	Cellesta Or Cellesta Duo, Per Square Centimeter.
Q4185	Cellesta Flowable Amnion (25 Mg Per Cc); Per 0.5 Cc.

Q4186	Epifix, Per Square Centimeter.
Q4187	Epicord, Per Square Centimeter.
Q4188	Amnioarmor, Per Square Centimeter.
Q4189	Artacent Ac, 1 Mg.
Q4190	Artacent Ac, Per Square Centimeter.
Q4191	Restorigin, Per Square Centimeter.
Q4192	Restorigin, 1 Cc.
Q4194	Novachor, Per Square Centimeter.
Q4195	Puraply, Per Square Centimeter.
Q4198	Genesis Amniotic Membrane, Per Square Centimeter.
Q4201	Matrion, Per Square Centimeter.
Q4204	Xwrap, Per Square Centimeter.
Q4205	Membrane Graft Or Membrane Wrap, Per Square Centimeter.
Q4208	Novafix, Per Square Centimeter.
Q4209	Surgraft, Per Square Centimeter.
Q4210	Axolotl Graft Or Axolotl Dulagraft, Per Square Centimeter.
Q4211	Amnion Bio Or Axobiomembrane, Per Square Centimeter.
Q4214	Cellesta Cord, Per Square Centimeter.
Q4216	Artacent Cord, Per Square Centimeter.
Q4217	Woundfix, Biowound ,Woundfix Plus, Biowound Plus, Woundfix Xplus Or Biowound Xplus, Per Square Centimeter.
Q4218	Surgicord, Per Square Centimeter.
Q4219	Surgigraft-dual, Per Square Centimeter
Q4221	Amniowrap2, Per Square Centimeter.
Q4227	Aniocore, Per Square Centimeter.
Q4229	Cogenex Amniotic Membrane, Per Square Centimeter.
Q4230	Cogenex Flowable Amnion, Per 0.5 Cc.
Q4231	Corpex P, Per Cc.
Q4232	Corpex, Per Square Centimeter.
Q4233	Surfactor Or Nudyn, Per 0.5 Cc.
Q4234	Xcellerate, Per Square Centimeter.
Q4235	Amniorepair Or Altiplay, Per Square Centimeter.
Q4237	Cryo-cord, Per Square Centimeter.

Q4239	Amnio-maxx Or Amnio-maxx Lite, Per Square Centimeter.
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	Coretex Or Protex, Per Cc.
Q4247	Amniotext Patch, Per Square Centimeter.
Q4248	Dermacyte Amniotic Membrane Allograft, Per Square Centimeter.
Q4249	Amnipliy, For Topical Use Only, Per Square Centimeter.
Q4250	Amnioamp-mp, Per Square Centimeter.
Q4254	Novafix DI, Per Square Centimeter.
Q4255	Reguard, For Topical Use Only, Per Square Centimeter.
V2790	Amniotic Membrane For Surgical Reconstruction, Per Procedure.

Covered Diagnosis Codes for Procedure Codes Q4132, Q4151 Q4154, Q4168 and Q4186
***L97 codes must be billed with one of the following codes from this section: E08.621-E13.622**

E08.621	E08.622	E09.621	E09.622	E10.621
E10.622	E11.621	E11.622	E13.621	E13.622
L97.111	L97.112	L97.113	L97.114	L97.115
L97.116	L97.118	L97.121	L97.122	L97.123
L97.124	L97.125	L97.126	L97.128	L97.201
L97.202	L97.203	L97.204	L97.211	L97.212
L97.213	L97.214	L97.215	L97.216	L97.218
L97.221	L97.222	L97.223	L97.224	L97.225
L97.226	L97.228	L97.301	L97.302	L97.303
L97.304	L97.311	L97.312	L97.313	L97.314
L97.315	L97.316	L97.318	L97.321	L97.322
L97.323	L97.324	L97.325	L97.326	L97.328
L97.401	L97.402	L97.403	L97.404	L97.411
L97.412	L97.413	L97.414	L97.415	L97.416
L97.418	L97.421	L97.422	L97.423	L97.424
L97.425	L97.426	L97.428	L97.501	L97.502
L97.503	L97.504	L97.511	L97.512	L97.513
L97.514	L97.515	L97.516	L97.518	L97.521

L97.522	L97.523	L97.524	L97.525	L97.526
L97.528	L97.801	L97.802	L97.803	L97.804
L97.811	L97.812	L97.813	L97.814	L97.815
L97.816	L97.818	L97.821	L97.822	L97.823
L97.824	L97.825	L97.826	L97.828	L97.901
L97.902	L97.903	L97.904	L97.911	L97.912
L97.913	L97.914	L97.915	L97.916	L97.918
L97.921	L97.922	L97.923	L97.924	L97.925
L97.926	L97.928			

Covered Diagnosis Codes for Q4133 *L97 codes must be billed with one of the following codes from this section: E08.621-E13.622

E08.621	E08.622	E09.621	E09.622	E10.621
E10.622	E11.621	E11.622	E13.621	E13.622
I83.001	I83.011	I83.021	I83.201	I83.211
I83.221	I83.002	I83.012	I83.022	I83.202
I83.212	I83.222	I83.003	I83.013	I83.023
I83.203	I83.213	I83.223	I83.004	I83.014
I83.024	I83.204	I83.214	I83.224	I83.005
I83.015	I83.025	I83.205	I83.215	I83.225
I83.008	I83.018	I83.028	I83.208	I83.218
I83.228	I83.009	I83.019	I83.029	I83.209
I83.219	I83.229	L97.111	L97.112	L97.113
L97.114	L97.211	L97.212	L97.213	L97.214
L97.215	L97.216	L97.218	L97.221	L97.222
L97.223	L97.224	L97.225	L97.226	L97.228
L97.301	L97.302	L97.303	L97.304	L97.311
L97.312	L97.313	L97.314	L97.315	L97.316
L97.318	L97.321	L97.322	L97.323	L97.324
L97.325	L97.326	L97.328	L97.401	L97.402
L97.403	L97.404	L97.411	L97.412	L97.413
L97.414	L97.415	L97.416	L97.418	L97.421
L97.422	L97.423	L97.424	L97.425	L97.426
L97.428	L97.501	L97.502	L97.503	L97.504
L97.511	L97.512	L97.513	L97.514	L97.515
L97.516	L97.518	L97.521	L97.522	L97.523
L97.524	L97.525	L97.526	L97.528	L97.801

L97.802	L97.803	L97.804	L97.811	L97.812
L97.813	L97.814	L97.815	L97.816	L97.818
L97.821	L97.822	L97.823	L97.824	L97.825
L97.826	L97.828	L97.901	L97.902	L97.903
L97.904	L97.911	L97.912	L97.913	L97.914
L97.915	L97.916	L97.918	L97.921	L97.922
L97.923	L97.924	L97.925	L97.926	L97.928

Covered Diagnosis Codes for Procedure Codes 65779, Q4100 and V2790

H11.001	H11.002	H11.003	H11.011	H11.012
H11.013	H11.021	H11.022	H11.023	H11.031
H11.032	H11.033	H11.041	H11.042	H11.043
H11.051	H11.052	H11.053	H11.061	H11.062
H11.063	H16.001	H16.002	H16.003	H16.011
H16.012	H16.013	H16.021	H16.022	H16.023
H16.031	H16.032	H16.033	H16.041	H16.042
H16.043	H16.051	H16.052	H16.053	H16.061
H16.062	H16.063	H16.071	H16.072	H16.073
H16.231	H16.232	H16.233	H18.501	H18.502
H18.503	H18.509	H18.511	H18.512	H18.513
H18.519	H18.521	H18.522	H18.523	H18.529
H18.531	H18.532	H18.533	H18.539	H18.541
H18.542	H18.543	H18.549	H18.551	H18.552
H18.553	H18.559	H18.591	H18.592	H18.593
H18.599	H18.831	H18.832	H18.833	L51.1

Covered Diagnosis Codes for procedure code 65778

H04.121	H04.122	H04.123	H04.129	H16.071
H16.072	H16.073	H16.079	H16.401	H16.402
H16.403	H16.409	H16.411	H16.412	H16.413
H16.419	H16.421	H16.422	H16.423	H16.429
H16.431	H16.432	H16.433	H16.439	H16.441
H16.442	H16.443	H16.449	H18.10	H18.11
H18.12	H18.13	H18.30	H18.52	H18.831
H18.832	H18.833	H18.839	H18.891	H18.892
H18.893	H18.899	I87.2	T26.10XA	T26.10XD

T26.10XS	T26.11XA	T26.11XD	T26.11XS	T26.12XA
T26.12XD	T26.12XS	T26.20XA	T26.20XD	T26.20XS
T26.21XA	T26.21XD	T26.21XS	T26.22XA	T26.22XD
T26.22XS	T26.31XA	T26.31XD	T26.31XS	T26.32XA
T26.32XD	T26.32XS	T26.40XA	T26.40XD	T26.40XS
T26.41XA	T26.41XD	T26.41XS	T26.42XA	T26.42XD
T26.50XA	T26.50XD	T26.50XS	T26.51XA	T26.51XD
T26.51XS	T26.52XA	T26.52XD	T26.52XS	T26.60XA
T26.60XD	T26.60XS	T26.61XA	T26.61XD	T26.61XS
T26.62XA	T26.62XD	T26.62XS	T26.70XA	T26.70XD
T26.70XS	T26.71XA	T26.71XD	T26.71XS	T26.72XA
T26.72XD	T26.72XS	T26.80XA	T26.80XD	T26.80XS
T26.81XA	T26.81XD	T26.81XS	T26.82XA	T26.82XD
T26.82XS	T26.90XA	T26.90XD	T26.90XS	T26.91XA
T26.91XD	T26.91XS	T26.92XA	T26.92XD	T26.92XS
T260.42XS				

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