

Policy: MP267

Section: Medical Benefit Policy

Subject: Amniotic Membrane Transplant for Ocular Surface Defects and Amniotic Injections

Applicable Lines of Business

Commercial	X	CHIP	X
Medicare	X	ACA	X
Medicaid	X		

I. Policy: Amniotic Membrane Transplant for Ocular Surface Defects and Amniotic Injections

II. Purpose/Objective:

To provide a policy of coverage regarding Amniotic Membrane Transplant for Ocular Surface Defects and Amniotic Injections

III. Responsibility:

- A. Medical Directors
- B. Medical Management

IV. Required Definitions

1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. Devised – the date the policy was implemented.
4. Revised – the date of every revision to the policy, including typographical and grammatical changes.
5. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

V. Additional Definitions

Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:

- a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- b. provided for the diagnosis, and the direct care and treatment of the Member's condition, illness disease or injury;
- c. in accordance with current standards of good medical treatment practiced by the general medical community.
- d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and
- e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

Medicaid Business Segment

Medically Necessary — A service, item, procedure, or level of care that is necessary for the proper treatment or management of an illness, injury, or disability is one that:

- Will, or is reasonably expected to, prevent the onset of an illness, condition, injury or disability.
- Will, or is reasonably expected to, reduce or ameliorate the physical, mental or developmental effects of an illness, condition, injury or disability.
- Will assist the Member to achieve or maintain maximum functional capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for Members of the same age

DESCRIPTION:

Amniotic membrane transplantation (AMT) is a procedure that utilizes amniotic membrane tissue to reconstruct damaged ocular surfaces and promote healing of corneal, conjunctival, and eyelid tissues after injury due to trauma, disease, or surgery. Human amniotic membrane grafts may also be used to treat lower extremity diabetic skin ulcers.

INDICATIONS:

Preserved human amniotic membrane transplantation may be considered medically necessary for the treatment of ocular surface defects including, but not limited to:

- Bullous keratopathy
- Chemical or thermal burns to ocular surface
- Corneal ulcerations
- Pterygium (either primary and/or recurrent)
- Stevens-Johnson syndrome
- Limbal cell deficiency
- Persistent epithelial defects
- Conjunctival surface reconstruction
- Refractory severe dry eye (DEWS* 3 or 4) with ocular surface damage
- Herpes zoster ophthalmicus

*Note: Dry eye severity level (DEWS) 3 to 4 is assessed based on the following 9 domains:

- Discomfort, severity, and frequency - Severe frequent or constant
- Visual symptoms - chronic and/or constant, limiting to disabling
- Conjunctival Injection - +/- or +/+
- Conjunctive Staining - moderate to marked
- Corneal Staining - marked central or severe punctate erosions
- Corneal/tear signs - Filamentary keratitis, mucus clumping, increase in tear debris
- Lid/meibomian glands - Frequent
- Tear film breakup time - < 5
- Schirmer score (mm/5 min) - < 5

Human amniotic membrane grafts will be considered medically necessary for the treatment of non-healing lower-extremity diabetic skin ulcers. **(See also: MP075)** Examples of these human amniotic membrane products include, but are not limited to:

- AmnioBand® Membrane
- Biovance®
- Epifix®
- GrafixCore™
- GrafixPrime™

EXCLUSIONS:

Injection of human amniotic fluid is considered unproven for all musculoskeletal indications including, but not limited to osteoarthritis and plantar fasciitis, musculoskeletal injuries, joint conditions, and all other conditions not identified above. There is insufficient evidence in the peer-reviewed published medical literature to establish the effectiveness of this service on health outcomes when compared to established treatments or technologies, and therefore are considered to be **NOT COVERED**.

Medicaid Business Segment:

Any requests for services that do not meet criteria set in the PARP may be evaluated on a case by case basis.

CODING ASSOCIATED WITH: Amniotic Membrane Transplant for Ocular Surface Defects and Amniotic Injections
The following codes are included below for informational purposes and may not be all inclusive. Inclusion of a procedure or device code(s) does not constitute or imply coverage nor does it imply or guarantee provider reimbursement. Coverage is determined by the member specific benefit plan document and any applicable laws

regarding coverage of specific services. Please note that per Medicare coverage rules, only specific CPT/HCPCS Codes may be covered for the Medicare Business Segment. Please consult the CMS website at www.cms.gov or the local Medicare Administrative Carrier (MAC) for more information on Medicare coverage and coding requirements

65778 – Placement of amniotic membrane on the ocular surface; without sutures
65779 - single layer, sutured
65780 – Ocular surface reconstruction; amniotic membrane transplantation, multiple layers
65781 limbal stem cell allograft (e.g., cadaveric or living donor)
65782 limbal conjunctival autograft (includes obtaining graft)
V2790 Amniotic membrane for surgical reconstruction, per procedure
Q4132 Grafix Core, per sq cm
Q4133 Grafix prime, grafixpl prime, stravax and stravaxpl, per square centimeter
Q4151 AmnioBand or Guardian, per sq cm
Q4154 Biovance, per sq cm
Q4168 AmnioBand, 1 mg
Q4186 Epifix, per square centimeter
Q4187 Epicord, per square centimeter

Current Procedural Terminology (CPT®) © American Medical Association: Chicago, IL

LINE OF BUSINESS:

Eligibility and contract specific benefits, limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy. For Medicare, applicable LCD's and NCD's will supercede this policy. For PA Medicaid Business segment, this policy applies as written.

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This policy will be revised as necessary and reviewed no less than annually.

Devised: 7/12

Revised: 7/19 (add indications and exclusions); 7/23 (add indication and associated info); 7/24 (add and refine exclusion)

Reviewed: 8/13, 8/14; 8/15; 7/16, 7/17, 6/18, 7/20, 7/21, 7/22

CMS UM Oversight Committee Approval: 12/23

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Coverage for experimental or investigational treatments, services and procedures is specifically excluded under the member's certificate with Geisinger Health Plan. Unproven services outside of an approved clinical trial are also specifically excluded under the member's certificate with Geisinger Health Plan. This policy does not expand coverage to services or items specifically excluded from coverage in the member's certificate with Geisinger Health Plan. Additional information can be found in MP015 Experimental, Investigational or Unproven Services.

Prior authorization and/or pre-certification requirements for services or items may apply. Pre-certification lists may be found in the member's contract specific benefit document. Prior authorization requirements can be found at <https://www.geisinger.org/health-plan/providers/ghp-clinical-policies>

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