Policy Name	Clinical Policy – Amniotic Membrane
Policy Number	1312.00
Department	Clinical Product & Strategy
Subcategory	Medical Management
Original Approval Date	03/21/2018
Current MPC/CCO Approval Date	01/03/2024
Current Effective Date	05/01/2024

Company Entities Supported (Select All that Apply)
_X_ Superior Vision Benefit Management
_X_ Superior Vision Services
_X_ Superior Vision of New Jersey, Inc.
_X_ Block Vision of Texas, Inc. d/b/a Superior Vision of Texas
_X_ Davis Vision
(Collectively referred to as 'Versant Health' or 'the Company')

ACRONYMS	
AM	Amniotic membrane

PURPOSE

To provide the medical necessity criteria to support the indication(s) for use of amniotic membrane. Applicable procedure codes are also defined.

POLICY

A. BACKGROUND

Amniotic membrane (AM) is used as a surgical graft and as a biological bandage. The properties of AM that are advantageous to ophthalmologists and optometrists include anti-inflammatory, anti-microbial, and low immunogenicity.

B. Medically Necessary

1. Amniotic Membrane grafting (65426, 65778, 65779, 65780, 65781, 65782, and 66999) is indicated for the following conditions:

    a. Chemical or thermal burns of the ocular surface
    b. Cicatricial pemphigoid

c. Corneal or scleral ulcer
d. Limbal stem cell deficiency
e. Persistent corneal epithelial defects
f. Stevens-Johnson syndrome
g. As a graft in pterygium surgery or after ocular surface tumor removal
h. High risk keratoplasty or keratectomy
i. Scarring after strabismus surgery
j. High risk trabeculectomy
k. Patch graft to cover all or part of an extraocular aqueous shunt
l. Persistent ocular surface disease after application of a bandage contact lens
m. Symblepharon and fornix reconstruction

2. Amniotic Membrane grafting (65778) for keratitis sicca syndrome requires demonstration of unresponsiveness to the following trial treatments:

   a. A two-month trial of artificial tears; and,
   b. punctal plugs; and,
   c. A three-month trial of topical cyclosporine-A 0.05% or .09% ophthalmic emulsion (e.g., Restasis or Cequa); or
   d. A three-month trial of a lymphocyte function associated antigen-1 receptor blocker (e.g., Lifitegrast).

3. Repeat or multiple applications of AM to the same site are rarely necessary. Chart documentation must describe the medical rationale for a repeat AM.

C. Documentation

Medical necessity must be supported by adequate and complete documentation in the patient's medical record that describes the procedure and the medical rationale for it as in the requirements above. All items must be available upon request to initiate or sustain previous payments. For any retrospective review, a full operative report is needed.

Every page of the record must be legible and include appropriate patient identification information (e.g., complete name, date(s) of service). Services provided/ordered must be authenticated by the physician, in a handwritten or electronic signature. Stamped signatures are not acceptable.

Medical justification for amniotic membrane use includes documentation of the patient's eye exam with treatment goals for AM that are consistent with the manufacturer's directions for use in the product insert.

D. Procedural Detail

CPT / HCPCS Codes	
65426	Excision or transposition of pterygium; with graft
65778	Placement of amniotic membrane on the ocular surface; without sutures; do not use with tissue glue

65779	Placement of amniotic membrane on the ocular surface; single layer, sutured; do not use with tissue glue
65780	Ocular surface reconstruction; amniotic membrane transplantation, multiple layers; do not use tissue glue
65781	Ocular surface reconstruction; limbal stem cell allograft (e.g., cadaveric or living donor)
65782	Ocular surface reconstruction: limbal conjunctival autograft (includes obtaining graft)
66999	Unlisted procedure, anterior segment of eye (for tissue glue used with amniotic membrane)
Q4280	Xcell Amnio Matrix, per sq cm
Q4283	Biovance Tri-Layer or Biovance 3L, per sq cm
V2790	Amniotic membrane for surgical reconstruction, per procedure. Use with 66999 and 65426. Do not combine use with 65778, 65779, 65780.
Required Modifiers	
Anatomical Modifiers	RT LT, or 50
Invalid Modifiers	
Diagnostic Modifiers	TC and 26 There is no technical component of a surgical code because this service cannot be delegated to a medical assistant or ophthalmic technician; TC and 26 are not valid modifiers to append to any of the codes above.
EM Modifiers	Surgery codes do not allow for EM modifiers. Modifiers 24, 25, 57, and 95 are not allowed to be appended to any surgery code.

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RELATED POLICIES AND PROCEDURES	
1311	Adult Strabismus Surgery
1332	Punctal Plugs

DOCUMENT HISTORY		
Approval Date	***Revision***	***Effective Date***
03/21/2018	Initial Policy	03/21/2018
03/29/2019	Annual review; no criteria changes.	03/29/2019
02/19/2020	Annual review; no criteria changes.	04/01/2020
01/06/2021	Annual review; no criteria changes.	04/01/2021
01/05/2022	Annual review; addition of CPT codes 65781 and 65782	04/01/2022
01/04/2023	Annual review; added indications for scleral ulcer, ocular surface tumor removal, scarring after strabismus surgery; added range in drug strength; added separate criteria for keratitis sicca; differentiated criteria for surgical and nonsurgical uses of amniotic membrane.	07/01/2023
09/20/2023	Administrative review for CMS 2024 final rule Medicare Part C equity: no changes.	n/a
01/03/2024	Annual review; no criteria changes; add new HCPCS codes Q4280 and Q4283.	05/01/2024

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