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QUESTION: What is PROKERA®?

ANSWER: According to the manufacturer, the [PROKERA](#) family of products are corneal-epithelial inserts consisting of an ophthalmic conformer that incorporates one or two layers of cryopreserved amniotic membrane; it is inserted between the eyeball and the eyelid and is self-retained on the eye. PROKERAs are Class II medical devices that serve as biologic corneal bandages. The CryoTek® processed tissue retains the key biologic components of the amniotic membrane that are anti-inflammatory, anti-scarring, anti-angiogenic, promote limbal stem-cell proliferation and wound healing. The FDA approval notes that it may remain in place up to 29 days. However, most uses of PROKERA will see natural dissolution of the membrane in about 3-7 days, at which point the conformer can be removed; it may be removed earlier if the patient's condition improves.

The PROKERA family of products includes PROKERA, PROKERA Slim, PROKERA Plus, and PROKERA Clear.

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QUESTION: What CPT code describes administration of PROKERA?

ANSWER: CPT code 65778 describes this procedure.

In 2014, CPT amended the code descriptor for 65778 from the original, which had existed since 2011. The descriptor currently reads, "*Placement of amniotic membrane on the ocular surface; without sutures*".

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QUESTION: Does Medicare cover placement of a PROKERA biologic corneal bandage?

ANSWER: Yes, when medically necessary.

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QUESTION: What are the indications for PROKERA?

ANSWER: It is used to maintain space in the orbital cavity between the eyeball and the eyelid, and to prevent closure or adhesion. It is also used to facilitate healing in which the ocular surface cells have been damaged, or the underlying stroma is inflamed or scarred. Some conditions for which it may be used include:¹

- Chemical burns of the ocular surface
- Corneal epithelial defects, such as may be encountered clinically with:
 - Bullous or band keratopathy
 - Epithelial basement membrane dystrophy
 - Recurrent corneal erosions
 - Keratitis (exposure, neurotrophic, filamentary, bacterial or viral)
 - Post-op care after corneal procedures
 - Post-op care after pterygium surgery
- Corneal ulcer
- Partial limbal stem-cell deficiency
- Persistent epithelial defects (delayed healing)
- Stevens-Johnson Syndrome

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QUESTION: What is the Medicare allowed amount for physicians performing 65778?

ANSWER: Payment rates vary by site of service. In 2020, the Medicare Physician Fee Schedule allowed amounts are:

- | | |
|---------------------------|---------|
| • Physician (in-office) | \$1,436 |
| • Physician (in-facility) | \$56 |

These amounts are adjusted in each locality by local indices. Other payers set their own fee schedules, which may differ considerably from Medicare rates.

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QUESTION: What does Medicare allow as a facility fee for 65778?

ANSWER: In 2020, the Medicare facility fee for hospital outpatient department (HOPD) is \$807; this includes payment for the device. This amount is adjusted in each locality by local indices. Other payers set their own fee schedules, which may differ considerably from Medicare rates.

At present, there is no facility fee for 65778 for an ambulatory surgery center (ASC).

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QUESTION: Does Medicare pay for the supply of PROKERA separately?

ANSWER: No. HCPCS code V2790, “Amniotic membrane for surgical reconstruction per procedure”, is no longer eligible for discrete Medicare payment in any setting. Reimbursement for the supply is included with payment for the procedure.

The large site-of-service difference noted in Box #5, between physician reimbursement in-office and in-facility, is due to the inclusion of PROKERA in the facility payment.

As with any payment rates, other payers may have different policies regarding the supply of PROKERA. Check with your payers.

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QUESTION: What is the postoperative surgical period for 65778?

ANSWER: The global surgery period for 65778 is zero days in 2018; this is a change from the “10 days” global period in 2015 and earlier.

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QUESTION: How am I reimbursed for using PROKERA during the postoperative period of another procedure?

ANSWER: Reimbursement depends on why and where you administer PROKERA.

If PROKERA is applied during an exam in a lane or minor treatment room to deal with an unanticipated complication of a prior surgery, your earlier payment for the prior procedure includes postoperative care, including supply of PROKERA.

If the use of PROKERA is preplanned as part of a staged or anticipated treatment, use 65778-58 on your claim. For example, use of PROKERA during the postoperative period of penetrating keratoplasty for high-rejection-risk patients may improve corneal graft survival. The medical record should support this rationale.

If PROKERA is applied for a reason unrelated to the prior surgery, in any setting, use 65778-79. For example, to address a problem in the fellow eye.

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QUESTION: How is PROKERA reimbursed when used after corneal surgery?

ANSWER: In cases of persistent corneal epithelial defects or delayed healing following corneal procedures, PROKERA can aid the healing process when re-epithelization isn't satisfactory in 4-5 days.

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¹ Not a complete list. For the FDA package inserts, [link here](#).

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