EX-PRESS® Glaucoma Filtration Device Coding and Billing Guide

EX-PRESS® Glaucoma Filtration Device Description and Indication

The EX-PRESS® Glaucoma Filtration Device received FDA clearance on March 26, 2002. The device is a mini glaucoma shunt and is intended to reduce intraocular pressure in glaucoma patients where medical and conventional surgical treatments have failed.

Procedure and Device Coding

The EX-PRESS® Glaucoma Filtration Device should be reported using Current Procedural Terminology (CPT®) Category I Code, 66183, insertion of anterior segment aqueous drainage device, without extraocular reservoir; external approach. HCPCS codes used to report the EX-PRESS® Glaucoma Filtration Device are C1783, ocular implant, aqueous drainage assist device, or L8612, aqueous shunt.

<table>
<thead>
<tr>
<th>Payer Type</th>
<th>Physician</th>
<th>Ambulatory Surgery Center</th>
<th>Hospital Outpatient</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medicare</td>
<td>66183</td>
<td></td>
<td>66183 and C1783 Ocular Implant</td>
</tr>
<tr>
<td>Commercial</td>
<td>66183</td>
<td></td>
<td>66183 and L8612 Aqueous shunt</td>
</tr>
</tbody>
</table>

Diagnosis Coding

Diagnosis coding is determined by the patient’s condition. The ICD-10-CM codes listed below are commonly associated with patients receiving the EX-PRESS® Glaucoma Filtration Device. This is not an all inclusive list of diagnoses codes. The list below is not intended to provide an exhaustive list of all possible diagnosis codes. It is the providers responsibility to report the ICD-10 code that most accurately describes the patient’s condition.

<table>
<thead>
<tr>
<th>ICD-10-CM</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>H40.1 through H40.10</td>
<td>Open-angle glaucoma</td>
</tr>
<tr>
<td>H40.10X0</td>
<td>Unspecified open-angle glaucoma, state unspecified</td>
</tr>
<tr>
<td>H40.10X1</td>
<td>Unspecified open-angle glaucoma, mild stage</td>
</tr>
<tr>
<td>H40.10X2</td>
<td>Unspecified open-angle glaucoma, moderate stage</td>
</tr>
<tr>
<td>H40.10X3</td>
<td>Unspecified open-angle glaucoma, severe stage</td>
</tr>
<tr>
<td>H40.10X4</td>
<td>Unspecified open-angle glaucoma, intermediate stage</td>
</tr>
</tbody>
</table>

See Important Product Information on back.
Use code 66183, Insertion of anterior segment aqueous drainage device, without extraocular reservoir; external approach for Medicare and private payers.

Enter appropriate diagnosis code(s).

Use code 66183. Insertion of anterior segment aqueous drainage device, without extraocular reservoir; external approach for Medicare and private payers.

Include appropriate modifiers (i.e., -RT or -LT).

This information is provided for informational purposes only. It does not constitute legal or reimbursement advice or recommendations regarding clinical practice. Alcon makes no guarantee that use of this information will result in coverage or payment or prevent disagreement by payers with regard to billing, coverage or amount of payment. Alcon encourages providers to submit accurate and appropriate claims for services. It is always the provider’s responsibility to determine medical necessity, the proper site for delivery of any services and to submit accurate information, codes, charges, and modifiers for services that are rendered. Coding, coverage and payment policies are complex and are frequently updated. Alcon recommends that you consult with your legal counsel, applicable payers’ policies or reimbursement specialists regarding coding, coverage and reimbursement.
Insertion of anterior segment aqueous drainage device, without extraocular reservoir, external approach

FOR MEDICARE, USE CODE 66183, Insertion of anterior segment aqueous drainage device, without extraocular reservoir, external approach

FOR COMMERCIAL PAYERS, USE BOTH CODES: 66183, Insertion of anterior segment aqueous drainage device, without extraocular reservoir, external approach, AND, L8612, Aqueous shunt.

Include appropriate modifiers (i.e., -RT or -LT)

When using a UB-04, refer to the Hospital Outpatient Claim Form Example.

See Important Product Information on back.
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Payment

Medicare and many commercial payers package reimbursement for the EX-PRESS® device with the facility payment. Facilities are encouraged to proactively review and negotiate their commercial payer contracts for payment of L8612.

2019 Medicare National Unadjusted Payment Rates*

<table>
<thead>
<tr>
<th></th>
<th>Physician</th>
<th>Ambulatory Surgery Center</th>
<th>Hospital Outpatient</th>
</tr>
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<tbody>
<tr>
<td></td>
<td>$1,055.59</td>
<td>$2,361.93</td>
<td>$3,640.26 (APC 5492)</td>
</tr>
</tbody>
</table>

NOTE: 66183 has a 90-day global period. Inclusion in a fee schedule is not a guarantee of payment. Special payment rules such as multi-procedure payment reduction, comprehensive ambulatory payment classification (C-APC) in the hospital outpatient setting, and other alternative payment models can impact actual reimbursement. Fees shown are national unadjusted payment and are subject to local wage adjustments. Source: CMS.gov

* As of January 2019, the EX-PRESS Glaucoma Filtration Device now qualifies as a device-intensive payment. Device-intensive procedures require the implantation of a device, meeting the following criteria:
  - All procedures must involve implantable devices that would be reported if device insertion procedures were performed;
  - The required devices must be surgically inserted or implanted devices that remain in the patient’s body after the conclusion of the procedure (at least temporarily); and
  - The device offset amount must be significant, which is defined as exceeding 30 percent of the procedure’s mean cost

Commercial Payer Reimbursement

Payment from commercial payers will be contingent upon individual contracts that may need to be updated to include CPT® code 66183. Like Medicare, many commercial payer contracts package the cost of the EX-PRESS® device with facility payment for CPT® code 66183, while other commercial payers may allow an additional payment for HCPCS L8612. Individual contracts are always proprietary to the provider.
CAUTION: Federal (USA) law restricts this device to sale by, or on the order of, a physician.

INDICATION: The EX-PRESS® Glaucoma Filtration Device is intended to reduce intraocular pressure in glaucoma patients where medical and conventional surgical treatments have failed.

GUIDANCE REGARDING THE SELECTION OF THE APPROPRIATE VERSION: Prior clinical studies were not designed to compare between the various versions of the EX-PRESS® Glaucoma Filtration Device. The selection of the appropriate version is according to the doctor’s discretion.

CLINICAL STUDY INFORMATION: A clinical study was performed with the EX-PRESS® Glaucoma Filtration Device versions R-30 and R-50. The study was a prospective, open-label multi-center study of 113 open angle glaucoma patients with a follow-up period of one year. Results indicated an 80.4% overall success for the per-protocol cohort (R-30 and R-50, n=58) at one year, where overall success was defined as an IOP reduction greater than 20% from baseline with or without medications. Results indicated a 75.9% overall success for the per-protocol cohort (R-30 and R-50, n=58) at one year, where overall success was defined as an IOP of less than 21 mmHg with or without medications. The mean IOP reduction at one year was 33.8%. The percentage reduction from baseline was greater than 28% for the R-30 version and greater than 40% for the R-50 version.

The overall average number of glaucoma medications dropped significantly from 1.55 pre-operative to 0.52 medications at one-year postoperative.

The clinical study was not designed to compare between the various versions of the EX-PRESS® Glaucoma Filtration Device. The selection of the appropriate version is according to the doctor’s discretion. The most commonly reported adverse events included the need for further filtering surgery, device explantation, bleb revision and iris touch. Reasons for device explantation included flat anterior chamber with hypotony, device exposure from erosion, and poor efficacy. Other adverse events such as, but not limited to, corneal and retinal complications, uveitis, and significant reduction in visual acuity, may occur as well.

CONTRAINDICATIONS: The use of this device is contraindicated if one or more of the following conditions exist:

Presence of ocular disease such as uveitis, ocular infection, severe dry eye, severe blepharitis.

Pre-existing ocular or systemic pathology that, in the opinion of the surgeon, is likely to cause postoperative complications following implantation of the device.

Patients diagnosed with angle closure glaucoma.

WARNINGS/PRECAUTIONS: The use of this device is contraindicated if one or more of the following conditions exist:

The surgeon should be familiar with the directions for use.

The integrity of the package should be examined prior to use and the device should not be used if the package is damaged and sterility is compromised.

This device is for single use only.

MRI of the head is permitted, however not recommended, in the first two weeks post implantation.

ATTENTION: Reference the Directions for Use labeling for a complete listing of indications, warnings, precautions, complications and adverse events.