XEN® Procedure
Comprehensive Billing and Coding Guide
(Rev: 02/2020)
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### Overview

This guide provides billing and coding information for physicians and facilities submitting claims for the XEN® procedure.

#### INDICATIONS

The XEN® Glaucoma Treatment System (XEN® 45 Gel Stent preloaded into a XEN® Injector) is indicated for the management of refractory glaucomas, including cases where previous surgical treatment has failed, cases of primary open-angle glaucoma, and pseudoxfoliative or pigmentary glaucoma with open angles that are unresponsive to maximum tolerated medical therapy.

#### IMPORTANT SAFETY INFORMATION

**CONTRAINDICATIONS**

XEN® Gel Stent is contraindicated in angle-closure glaucoma where angle has not been surgically opened, previous glaucoma shunt/valve or conjunctival scarring/pathologies in the target quadrant, active inflammation, active iris neovascularization, anterior chamber intraocular lens, intraocular silicone oil, and vitreous in the anterior chamber.

### Warnings

XEN® Gel Stent complications may include choroidal effusion, hyphema, hypotony, implant migration, implant exposure, wound leak, need for secondary surgical intervention, and intraocular surgery complications. Safety and effectiveness in neovascular, congenital, and infantile glaucoma has not been established. Avoid digital pressure following implantation of the XEN® Gel Stent to avoid the potential for implant damage.

#### PRECAUTIONS

Examine the XEN® Gel Stent and XEN® Injector in the operating room prior to use. Monitor intraocular pressure (IOP) postoperatively and if not adequately maintained, manage appropriately. Stop the procedure immediately if increased resistance is observed during implantation and use a new XEN® system. Safety and effectiveness of more than a single implanted XEN® Gel Stent has not been studied.

### ADVERSE EVENTS

The most common postoperative adverse events included best-corrected visual acuity loss of ≥ 2 lines (< 30 days 15.4%; > 30 days 10.8%; 12 months 6.2%), hypotony IOP < 6 mm Hg at any time (24.6%; no clinically significant consequences were associated, no cases of persistent hypotony, and no surgical intervention was required), IOP increase > 10 mm Hg from baseline (21.5%), and needing procedure (32.3%).

Caution: Federal law restricts this device to sale by or on the order of a licensed physician. Please see the accompanying full Directions for Use. Directions for Use are also available by calling 1-800-678-1605 or visiting [www.allergan.com/xen/usa.html](http://www.allergan.com/xen/usa.html). Please call 1-800-433-8871 to report an adverse event.

### DISCLAIMER

The purpose of this tool is to provide healthcare professionals with the information needed for billing and reimbursement for the XEN® procedure. This guide is provided for illustrative purposes only and does not constitute legal advice. The coding, coverage, and payment information included in this guide is subject to change in accordance with frequently changing laws, regulations, rules, and policies. Reimbursement policies will vary by payer and state. You should check the current laws, regulations, and payer coverage policies to confirm current coding, coverage, and billing requirements for the XEN® procedure. Allergan encourages healthcare providers to submit claims with accurate and appropriate codes, charges, and modifiers for the services rendered. It is always the provider’s responsibility to determine medical necessity and the proper site for delivery of any services, and to submit the appropriate codes. Healthcare professionals are ultimately responsible for all aspects of reimbursement. Codes must accurately reflect the patient’s condition, procedure performed, and products used.
Coding for the XEN® Procedure and Device

CODING OVERVIEW

Medical billing codes convert a narrative description of a procedure, device, drug, or disease into an alphanumeric or numeric code. Healthcare providers use these codes on payer claim forms to report medical services and/or items rendered to patients as well as patient diagnoses. Physicians use CPT® codes for all procedures and services they perform in all settings of care.

The following section of this guide will review the codes that may be applicable to the XEN® procedure. Allergan encourages healthcare providers to submit claims with accurate and appropriate codes, charges, and modifiers for the services rendered. It is always the provider’s responsibility to determine medical necessity and the proper site for delivery of any service and to submit the appropriate codes.

PROCEDURE CODING

The table below identifies the Category III CPT® codes for reporting the XEN® procedure. The Category III CPT® codes for the XEN® procedure are effective as of January 1, 2017.

Typically, Category III CPT® codes are subject to manual or additional review by payers because they need to make a decision about medical necessity (coverage) before issuing payment. Therefore, it is highly recommended that, when available, providers obtain prior authorization for the XEN® procedure and be prepared to submit additional information following the submission of the claim to substantiate medical necessity.

Note: Medicare Fee for Service (FFS) does not have a prior-authorization process for services like XEN® administration. However, some Medicare managed care plans do require prior authorization. It is always recommended that providers determine if prior authorization is required.

<table>
<thead>
<tr>
<th>CPT® CODE</th>
<th>DESCRIPTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>0449T</td>
<td>Insertion of aqueous drainage device, without extracocular reservoir, internal approach, into the subconjunctival space; initial device</td>
</tr>
<tr>
<td>+ 0450T</td>
<td>Insertion of aqueous drainage device, without extracocular reservoir, internal approach, into the subconjunctival space; each additional device. (List separately in addition to code for primary procedure.)</td>
</tr>
</tbody>
</table>

The safety and effectiveness of more than a single implanted XEN® Gel Stent has not been studied.

Note: Coverage and coding requirements vary by payer, so be sure to conduct an insurance verification to confirm coverage. This coding information contained herein is gathered from various resources and is subject to change. Nothing in this document is intended to serve as reimbursement advice, a guarantee of coverage, or a guarantee of payment for the XEN® Glaucoma Treatment System.

Some commercial payers for ASCs may require the HCPCS code, L8612.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

XEN® Gel Stent is contraindicated in angle-closure glaucoma where angle has not been surgically opened, previous glaucoma shunt/device or conjunctival scarring/pathologies in the target quadrant, active inflammation, active iris neovascularization, anterior chamber intraocular lens, intraocular silicone oil, and vitreous in the anterior chamber.

Please see additional Important Safety Information on the following pages.

DEVICE CODING

Medicare HOPD

On hospital claims submitted to Medicare, a device HCPCS code will need to be reported to include the associated charges for the XEN® Glaucoma Treatment System.

When billing the procedure in the hospital setting, both the CPT® code and the HCPCS code must be on the claim for it to be properly adjudicated. If the HCPCS code or the CPT® code is missing, the claim will not be processed by Medicare.

Currently, the XEN® procedure is not described by a specific Level II HCPCS code. However, there is an established nonspecific code for aqueous shunt device that the Centers for Medicare and Medicaid Services (CMS) recommend that users report on the Hospital Outpatient Department (HOPD) claim form (see Appendix 3). It is important to note that the reporting of a Level II HCPCS code for the product is required on HOPD claims, and, if omitted, the claim will not be processed.

<table>
<thead>
<tr>
<th>HCPCS CODE</th>
<th>DESCRIPTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>C1783</td>
<td>Ocular implant, aqueous drainage assist device</td>
</tr>
</tbody>
</table>

Although the reimbursement for the cost of the device will be included in the allowed amount assigned to CPT® code 0449T, it is still important to set appropriate charges for the Level II HCPCS code on the HOPD claim form. To ensure appropriate payment in the future, CMS uses retrospective total charges on claims to assign future payment rates.

Medicare ASC

Unlike hospitals, Ambulatory Surgery Centers (ASCs) do not need to report any additional device HCPCS codes to bill for XEN®. ASCs should include the charges associated with the device in the total charges for the procedure (CPT® code 0449T). See the sample claim form in Appendix 2 for additional information about ASC coding and billing for XEN®.

Commercial Payer ASC/HOPD

Commercial payer requirements may vary. It is advisable that the ASC/HOPD contact the payer for billing and coding directions for XEN® device coding.

Commercial payers may or may not require a code for the device. If a code is not required and services are bundled, it is imperative that the charges associated with the device are included in the total charges on the claim.

Some commercial payers for ASCs may require the HCPCS code, L8612.

<table>
<thead>
<tr>
<th>HCPCS CODE</th>
<th>DESCRIPTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>L8612</td>
<td>Ocular implant, aqueous drainage assist device</td>
</tr>
</tbody>
</table>

ICD-10-CM DIAGNOSIS CODING

Providers should report the appropriate ICD-10-CM diagnosis code(s) on third-party payer claim forms. The decision about which ICD-10-CM diagnosis code(s) to report must be made by the billing provider/physician considering the clinical facts, circumstances, and applicable coding rules, including the requirement to code to the highest level of specificity. The code(s) selected should be supported by the contents of any clinical notes and/or chart documentation. Please refer to your third-party payer policies for specific guidance.*

*Remember, ICD-10-CM codes submitted to the payer must accurately describe the diagnosis for which the patient receives the XEN® procedure, represent codes at the highest level of specificity, reflect the contents of any clinical notes and/or chart documentation, and be included in a letter of medical necessity or prior authorization.
### Coding for the XEN® Procedure and Device (continued)

#### MODIFIERS

Depending on the actual procedure(s) performed, it may be necessary to append certain modifiers to the CPT® codes on submitted claims. Modifiers are designed to provide payers with additional information that may be necessary to process claims. Healthcare providers may consider the coding options listed in the tables below and select the appropriate modifier(s) based on the procedure(s) performed.

**Right/Left Modifiers**

Providers should continue to use and report modifiers for practice and facility services on claims submitted to payers. Although ICD-10-CM diagnosis codes include details such as laterality descriptions (right, left, bilateral), Medicare recommends that providers continue to follow CPT® and Medicare guidance when reporting CPT®/HCPCS modifiers for laterality. The modifiers should be appended to CPT® code 0449T, as appropriate.

<table>
<thead>
<tr>
<th>MODIFIER</th>
<th>DESCRIPTION</th>
<th>DEFINITION</th>
</tr>
</thead>
<tbody>
<tr>
<td>-RT</td>
<td>Right side</td>
<td>Right side (used to identify procedures performed on the right side of the body)</td>
</tr>
<tr>
<td>-LT</td>
<td>Left side</td>
<td>Left side (used to identify procedures performed on the left side of the body)</td>
</tr>
</tbody>
</table>

**Multiple-Procedure Modifier**

A multiple-procedure modifier may be used to report the presence of multiple procedures. Modifier -51 is appended to the secondary procedure on the physician claim form (see Appendix 1).

<table>
<thead>
<tr>
<th>MODIFIER</th>
<th>DESCRIPTION</th>
<th>DEFINITION</th>
</tr>
</thead>
<tbody>
<tr>
<td>-51</td>
<td>Multiple procedures</td>
<td>Multiple procedures. When multiple procedures, other than E/M services, physical medicine, and rehabilitation services, or provision of supplies are performed at the same session by the same provider, the primary procedure or service may be reported as listed. The additional procedure(s) or service(s) may be identified by appending modifier -51 to the additional procedure or service code(s).</td>
</tr>
</tbody>
</table>

*This modifier should not be appended to designated “add-on” codes (e.g., 0450T).*

#### IMPORTANT SAFETY INFORMATION (continued)

**WARNINGS**

XEN® Gel Stent complications may include choroidal effusion, hyphema, hypotony, implant migration, implant exposure, wound leak, need for secondary surgical intervention, and intraocular surgery complications. Safety and effectiveness in neovascular, congenital, and infantile glaucoma has not been established. Avoid digital pressure following implantation of the XEN® Gel Stent to avoid the potential for implant damage.

**PRECAUTIONS**

Examine the XEN® Gel Stent and XEN® Injector in the operating room prior to use. Monitor intraocular pressure (IOP) postoperatively and if not adequately maintained, manage appropriately. Stop the procedure immediately if increased resistance is observed during implantation and use a new XEN® system. Safety and effectiveness of more than a single implanted XEN® Gel Stent has not been studied.

### Coding for the XEN® Procedure and Device (continued)

**Modifiers for Discontinued Procedures**

In the unforeseen event that the XEN® procedure is discontinued after the packaging for the XEN® Gel Stent System has been opened, certain modifiers can be used to report such an event to the payer.

<table>
<thead>
<tr>
<th>HCPCS CODE</th>
<th>DESCRIPTION</th>
<th>DEFINITION</th>
</tr>
</thead>
<tbody>
<tr>
<td>-53®</td>
<td>Discontinued procedure</td>
<td>Used by the physician when a surgical or diagnostic procedure is started but discontinued due to extenuating circumstances or those that threatened the well-being of the patient.</td>
</tr>
<tr>
<td>-73®</td>
<td>Discontinued Outpatient Hospital/Ambulatory Surgery Center (ASC) procedure prior to the administration of anesthesia</td>
<td>Used by the facility to indicate that a surgical or diagnostic procedure requiring anesthesia was terminated due to extenuating circumstances or those that threatened the well-being of the patient after the patient had been prepared for the procedure and taken to the procedure room, but before the administration of anesthesia (local, regional, or block).</td>
</tr>
<tr>
<td>-74®</td>
<td>Discontinued Outpatient Hospital/ASC procedure after administration of anesthesia</td>
<td>Used by the facility to indicate that a surgical or diagnostic procedure requiring anesthesia was terminated due to extenuating circumstances or those that threatened the well-being of the patient after the induction of anesthesia or after the procedure was started.</td>
</tr>
</tbody>
</table>

#### REVENUE CODES

Revenue codes are used on the HSPD UB-04 (CMS 1450) claim form (see Appendix 3). These codes are used to identify where the procedure was performed and to describe the general categories of services provided to the patient. Facilities are required to report revenue codes for each specific line of service. The following table lists some potentially relevant revenue codes.

<table>
<thead>
<tr>
<th>REVENUE CODE</th>
<th>DESCRIPTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>274</td>
<td>Medical/surgical supplies and devices, prosthetic/orthotic devices</td>
</tr>
<tr>
<td>278</td>
<td>Medical/surgical supplies and devices, other implants</td>
</tr>
<tr>
<td>360</td>
<td>Operating room services, general</td>
</tr>
<tr>
<td>490</td>
<td>Ambulatory surgical care, general</td>
</tr>
</tbody>
</table>

#### IMPORTANT SAFETY INFORMATION (continued)

**ADVERSE EVENTS**

The most common postoperative adverse events included best-corrected visual acuity loss of ≥ 2 lines (≥ 30 days 15.4%; > 30 days 10.8%; 12 months 6.2%), hypotony IOP < 6 mm Hg at any time (24.6%; no clinically significant consequences were associated, no cases of persistent hypotony, and no surgical intervention was required), IOP increase ≥ 10 mm Hg from baseline (21.5%), and needling procedure (32.3%).

Please see additional Important Safety Information on the following pages.
Coverage for the XEN® Procedure

PRIOR AUTHORIZATIONS AND APPEALS

Coverage policies describe what a health plan considers reasonable and necessary for the diagnosis and/or treatment of an illness or injury. To be covered service, the XEN® procedure must meet coverage requirements established by Medicare and commercial payers. Medicare and/or commercial payers may publish local coverage determinations and/or coverage policies (as applicable) that describe the circumstances under which the payer will cover the XEN® insertion procedure. In the absence of established coverage policies, payers will review prior authorizations and claims and determine coverage on a case-by-case basis.

It is important that physicians and facilities obtain prior authorization for the XEN® procedure (when required). It is anticipated that prior authorizations will be required for many commercial plans and some Medicare managed plans.

If a prior authorization is required and not completed, then the claim will be denied for failure to comply with the plan rules. This denial is very challenging to overturn.

It is expected that some prior authorizations may be denied. In the event of a denial, providers have several options:

Option 1: Secure an Advance Beneficiary Notice of Noncoverage (ABN) or patient financial responsibility form (see Appendix 4) if the beneficiary wants to have the procedure despite its noncoverage.
Option 2: Appeal the prior-authorization denial and postpone the surgery, if needed.
Option 3: Move forward with the procedure and be prepared to appeal the claim denial.

ADVANCE BENEFICIARY NOTICE

An ABN is a Medicare-specific form that is used when a provider believes that a payer may not pay for an item or service because of the payer’s policy concluding that the item or service is not reasonable and necessary. The payer may require that the provider have a patient sign an ABN form if the provider intends to bill the patient for such item or service.

• A tutorial and sample ABN form can be found here: www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/ABN-Tutorial/formCMSR131tutorial11915f.html
• To download the most current Medicare ABN form, refer to the CMS website, search for “Fee for Service Advance Beneficiary Notice of Noncoverage,” click on the “FFS ABN” link, then click on “ABN Forms English and Spanish (Inc Large Print)”

MODIFIER DESCRIPTION DESCRIPTION OF USE
GA Waiver of Liability Statement Issued as Required by Payer Policy, Individual Case Report when you issue a mandatory ABN for a service as required and it is on file. You do not need to submit a copy of the ABN, but you must have it available on request.
GX Notice of Liability Issued, Voluntary Under Payer Policy Report when you issue a voluntary ABN for a service Medicare never covers because it is statutorily excluded or is not a Medicare benefit. You may use this modifier in combination with modifier GY.
GY Item or Service Statutorily Excluded, Does Not Meet the Definition of Any MedicareBenefit Report that Medicare statutorily excludes the item or service, or the item or service does not meet the definition of any Medicare benefit. You may use this modifier in combination with modifier GY.

Providers should report modifier GZ (Item or Service Expected to be Denied as Not Reasonable and Necessary) when the provider expects Medicare to deny payment for the item or service due to lack of medical necessity, but no ABN was issued.

IMPORTANT SAFETY INFORMATION (continued)

CONTRAINDICATIONS

XEN® Gel Stent is contraindicated in angle-closure glaucoma where angle has not been surgically opened, previous glaucoma shunt/valve or conjunctival scarring/pathologies in the target quadrant, active inflammation, active iris neovascularization, anterior chamber intraocular lens, intraocular silicone oil, and vitreous in the anterior chamber.

Please see additional Important Safety Information on the following pages.
Reimbursement for the XEN® Procedure

After submitting a claim to an insurance company, healthcare providers are reimbursed for the episode of care as long as the services are considered medically reasonable and necessary. Outpatient surgeries such as the XEN® procedure will often have separate claims submitted for the physician payment and the facility payment.

### Facility Resources (Resources Used in Episode of Care)
- Ambulatory Surgery Centers (CMS 1500 claim form) (see a sample ASC claim form with instructions on page 15)
- Hospital Outpatient Departments (UB-04 CMS 1450 claim form) (see a sample HOPD claim form with instructions on page 16)

### Physician Resources (Resources Used in Episode of Care)
- Physicians (CMS 1500 claim form) (see a sample physician claim form with instructions on page 14)

Category III CPT® codes are used for reimbursement and tracking utilization and charges for some new technologies. The following sections describe the payment mechanisms used by Medicare and commercial payers.

#### MEDICARE REIMBURSEMENT

Medicare provides payments to providers based on fee schedules or prospective payment systems. Physicians are paid through the Medicare Physician Fee Schedule (MPFS), ASCs are paid through the Ambulatory Surgical Center Payment System, and HOPDs are paid through the Outpatient Prospective Payment System (OPPS). The following sections provide a brief overview of how Medicare sets reimbursement rates for procedures.

#### 2020 Medicare Payment Rates for XEN® Procedure (CPT® code 0449T)*

<table>
<thead>
<tr>
<th>Provider</th>
<th>Payment Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physician</td>
<td>Contractor-priced; no national payment rate set</td>
</tr>
<tr>
<td>Hospital Outpatient Department</td>
<td>APC 5492 (Level 2 Intraocular Procedures); $3817.90</td>
</tr>
<tr>
<td>Ambulatory Surgery Center</td>
<td>$2822.04</td>
</tr>
</tbody>
</table>

*The rates provided are the calendar year 2020 national, unadjusted OPPS, and ASC payment rates, respectively.

The payment information in the above table includes each payment rate assigned to CPT® code 0449T; however, inclusion of the payment rate is not a guarantee of payment.

IMPORTANT SAFETY INFORMATION (continued)

**WARNINGs**

XEN® Gel Stent complications may include choroidal effusion, hyphema, hypotony, implant migration, implant exposure, wound leak, need for secondary surgical intervention, and intraocular surgery complications. Safety and effectiveness in neovascular, congenital, and infantile glaucoma has not been established. Avoid digital pressure following implantation of the XEN® Gel Stent to avoid the potential for implant damage.

### Reimbursement for the XEN® Procedure (continued)

**Medicare Physician Reimbursement**

Physicians are paid according to the MPFS. Payments are calculated by multiplying the relative value units (RVUs) assigned to a CPT® code by the standard conversion factor in a given year.

Medicare assigns the relative value of a procedure as a measure of the physician’s work, the practice expense, and the malpractice/ professional liability insurance cost for the practice. The more skill-, time-, and labor-intensive a procedure is, the higher the RVUs and payment established for the corresponding CPT® code will be. For physician payment, CMS assigns national payment rates to Category I CPT® codes but not Category III CPT® codes.

Because Medicare does not set national payment rates for physician reimbursement for the XEN® procedure, it is very important that providers do the following:

- Appropriately set charges
- Keep detailed chart notes about the level of work involved for this procedure
- Monitor payments closely, and appeal if the payment is too low

While Medicare does not set national payment rates for Category III CPT® codes, individual Medicare Administrative Contractors (MACs) may set payment amounts. To find this information, it is recommended that you visit your individual MAC website and use the Fee Schedule Lookup tool.

**Medicare Facility Reimbursement**

Medicare hospital outpatient reimbursement is made based on Ambulatory Payment Classifications (APCs). Each APC contains procedures/services that are clinically similar and require similar resources. Each APC has a prospective payment amount based on the services assigned to that APC. Information submitted on claims is used for future rate setting.

To set prospective payments, CMS uses the retrospective data from information used on past claims to set APC rates. Therefore, it is important for the hospital to accurately report charges for any services that they render (inclusive of devices).

Medicare Ambulatory Surgery Center reimbursement uses the HOPD OPPS as a guide to set payment rates in the ASC setting. The ASC claims processing system differs from that of the HOPD; therefore, no device-specific HCPCS code is required for the processing and payment of the ASC claim. The charges for the device should be included in the total charges for the procedure (CPT® code 0449T). The reimbursement for the device will be included in the procedure reimbursement on the ASC claim.

**IMPORTANT SAFETY INFORMATION (continued)**

**PRECAUTIONS**

Examine the XEN® Gel Stent and XEN® Injector in the operating room prior to use. Monitor intraocular pressure (IOP) postoperatively and if not adequately maintained, manage appropriately. Stop the procedure immediately if increased resistance is observed during implantation and use a new XEN® system. Safety and effectiveness of more than a single implanted XEN® Gel Stent has not been studied.

Please see additional Important Safety Information on the following pages.
COMMERCIAL PAYER REIMBURSEMENT

Commercial payers generally do not make their payment rates public. There is considerable variability in how commercial payers reimburse for and cover the services provided to their members. Commercial payers may use the following mechanisms to determine payments to institutional providers and physicians in any setting of care:

- Preset rates through established contracts with specific providers
- Percentage of billed charges
- Per-diem rates
- Payment based on Medicare rates
- Payment groups similar to the Medicare prospective payment systems

Payment and coverage for Category III CPT® codes vary and may require a manual review by the payer. Because there are no publicly available commercial payment rates for the XEN® procedure, it is important that the provider get prior authorization (PA) for the procedure (when required), keep detailed chart notes, and check their provider contracts.

DISCLAIMER:
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ADVERSE EVENTS

The most common postoperative adverse events included best-corrected visual acuity loss of ≥ 2 lines (< 30 days 15.4%; > 30 days 10.8%; 12 months 6.2%), hypotony IOP < 6 mm Hg at any time (24.6%; no clinically significant consequences were associated, no cases of persistent hypotony, and no surgical intervention was required), IOP increase ≥ 10 mm Hg from baseline (21.5%), and needling procedure (32.3%).

IMPORTANT SAFETY INFORMATION (continued)

XEN® REIMBURSEMENT SUPPORT IS AVAILABLE:

Through your local Reimbursement Business Advisor

- Your local RBA can advise on billing, coding, and payer approval requisites; educate staff on reimbursement; and facilitate payer access
- Your local RBA stays in close communication with Allergan EyeCue® case managers to ensure your reimbursement needs are met

Through the Allergan EyeCue® call center at 1-855-XEN45-4U (1-855-936-4548)

CONTACT US

Phone: 1-855-XEN45-4U (1-855-936-4548); 9:00 am to 8:00 pm ET, option 2
Email: XENECS@priahealthcare.com
Fax: 1-860-782-2092

IMPORTANT SAFETY INFORMATION (continued)

Caution: Federal law restricts this device to sale by or on the order of a licensed physician. Please see the accompanying full Directions for Use. Directions for Use are also available by calling 1-800-678-1605 or visiting www.allergan.com/xen/usa.htm. Please call 1-800-433-8871 to report an adverse event.

Please see additional Important Safety Information on the following pages.
Appendix 1:
Physician CMS 1500 Sample Claim Form

Appendix 2:
ASC CMS 1500 Sample Claim Form

IMPORTANT SAFETY INFORMATION (continued)

CONTRAINDICATIONS

XEN® Gel Stent is contraindicated in angle-closure glaucoma where angle has not been surgically opened, previous glaucoma shunt/valve or conjunctival scarring/pathologies in the target quadrant, active inflammation, active iris neovascularization, anterior chamber intraocular lens, intracameral silicone oil, and vitreous in the anterior chamber.

WARNINGs

XEN® Gel Stent complications may include choroidal effusion, hyphema, hypotony, implant migration, implant exposure, wound leak, need for secondary surgical intervention, and intrascleral surgery complications. Safety and effectiveness in neovascular, congenital, and infarct glaucoma has not been established. Avoid digital pressure following implantation of the XEN® Gel Stent to avoid the potential for implant damage.

Please see additional Important Safety Information on the following pages.
Appendix 3: HOPD UB-04 (CMS 1450) Sample Claim Form

Appendix 4: Advance Beneficiary Notice of Noncoverage (ABN) Form

(Continued) IMPORTANT SAFETY INFORMATION

PRECAUTIONS

Examine the XEN® Gel Stent and XEN® Injector in the operating room prior to use. Monitor intraocular pressure (IOP) postoperatively and if not adequately maintained, manage appropriately. Stop the procedure immediately if increased resistance is observed during implantation and use a new XEN® system. Safety and effectiveness of more than a single implanted XEN® Gel Stent has not been studied.
CONTRAINDICATIONS

XEN® Gel Stent is contraindicated in angle-closure glaucoma where angle has not been surgically opened, previous glaucoma shunt/valve or conjunctival scoring/pathologies in the target quadrant, active inflammation, active iris neovascularization, anterior chamber intraocular lens, intraocular silicone oil, and vitreous in the anterior chamber.

WARNINGS

XEN® Gel Stent complications may include choroidal effusion, hyphema, hypotony, implant migration, implant exposure, wound leak, need for secondary surgical intervention, and intraocular surgery complications. Safety and effectiveness in neovascular, congenital, and infantile glaucoma has not been established. Avoid digital pressure following implantation of the XEN® Gel Stent to avoid the potential for implant damage.

PRECAUTIONS

Examine the XEN® Gel Stent and XEN® Injector in the operating room prior to use. Monitor intraocular pressure (IOP) postoperatively and if not adequately maintained, manage appropriately. Stop the procedure immediately if increased resistance is observed during implantation and use a new XEN® system. Safety and effectiveness of more than a single implanted XEN® Gel Stent has not been studied.

ADVERSE EVENTS

The most common postoperative adverse events included best-corrected visual acuity loss of ≥ 2 lines (≤ 30 days 15.4%; > 30 days 10.8%; 12 months 6.2%), hypotony IOP < 6 mm Hg at any time (24.6%; no clinically significant consequences were associated, no cases of persistent hypotony, and no surgical intervention was required), IOP increase ≥ 10 mm Hg from baseline (21.5%), and needling procedure (32.3%).

Caution: Federal law restricts this device to sale by or on the order of a licensed physician. Please see the accompanying full Directions for Use. Directions for Use are also available by calling 1-800-678-1605 or visiting www.allergan.com/xen/usa.htm. Please call 1-800-433-8871 to report an adverse event.

REFERENCES

3. WPS Government Health Administrators. Modifier 53 fact sheet. WPS website. https://www.wpsgha.com/wps/portal/mac/site/claims/guides-and-resources/moificado-53/tip/pcjo1y95048xwFEX_jq989as5S3a9eT2Qy0oy0x1w15G9W8h69-e9FaFjz6e_v-uI4com08k3u2km0V0VT7_3HFY9JN-G9y6I3yX9W39IhXYX37NL19w9S8h9thJUBB8y-6Nd49g2jnXyQq0hKh9WJLBX-JREKy6m5Mp9y19v3-wU4G60KvlKl0q4gqy4M9v5Gw2B2Xyqg4aUTfgr1JUBB8s0z32C3b7-nwBaow-WA/. Accessed January 23, 2020.