The XEN® Gel Stent Procedure

Billing and Coding Guide

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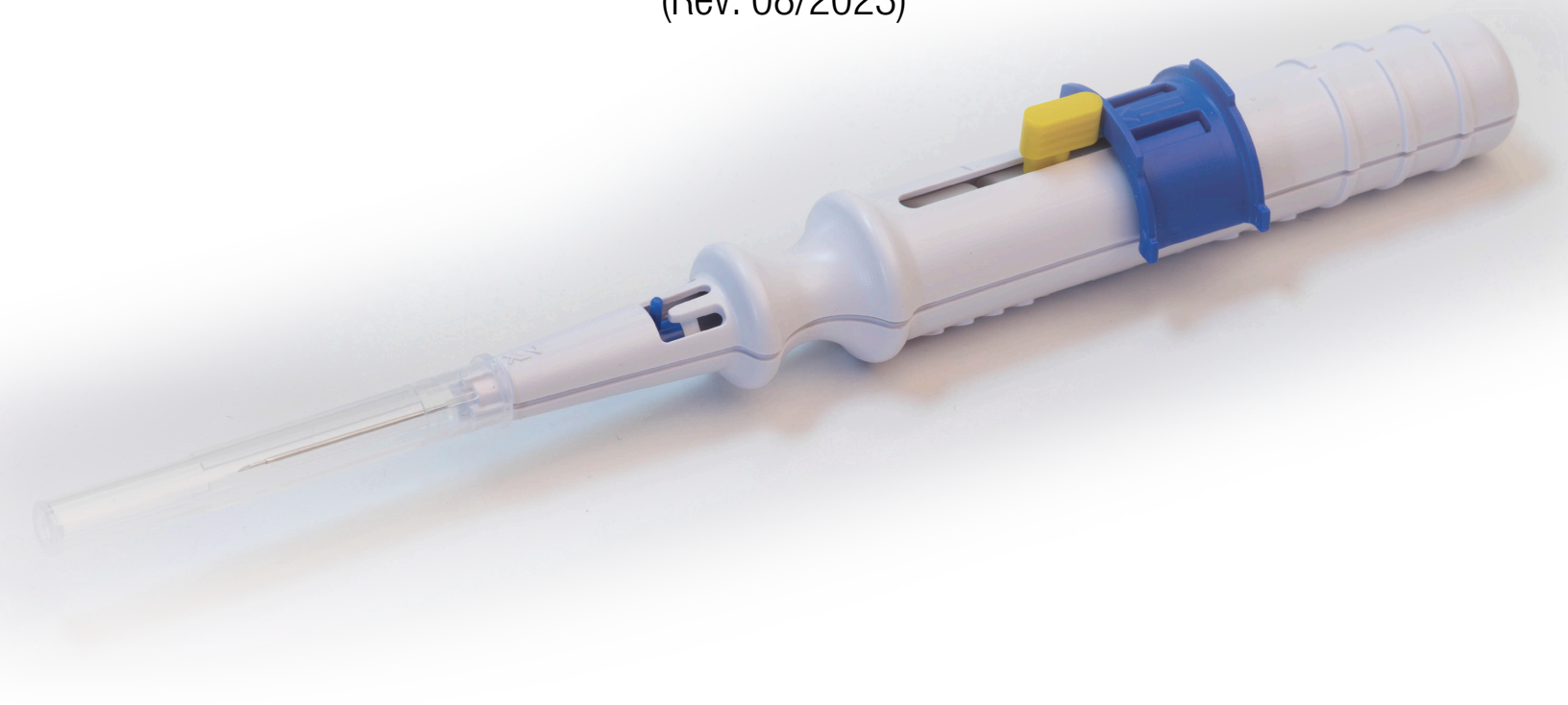

GEL STENT

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Overview

This guide provides billing and coding information for physicians and facilities submitting claims for the XEN® Gel Stent 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 pseudoexfoliative 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 needling procedure (32.3%).

Caution: Federal law restricts this device to sale by or on the order of a licensed physician. For the full Directions for Use, please visit www.allergan.com/xen/usa.htm or call 1-800-678-1605. Please call 1-800-433-8871 to report an adverse event.

Please see accompanying full Directions for Use or visit https://www.rxabbvie.com/pdf/xen_dfu.pdf

DISCLAIMER:
This guide is for informational purposes only and is not intended to provide reimbursement or legal advice. The information presented here does not guarantee payment or coverage. 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® Gel Stent procedure. Allergan, an AbbVie company, 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.

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Coding for the XEN® Gel Stent 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® Gel Stent procedure. Allergan, an Abbvie company, 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

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® Gel Stent 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® Gel Stent administration. However, some Medicare managed care plans do require prior authorization. It is always recommended that providers determine if prior authorization is required.

CPT® CODE	DESCRIPTION
0449T	Insertion of aqueous drainage device, without extraocular reservoir, internal approach, into the subconjunctival space; initial device
+ 0450T	Insertion of aqueous drainage device, without extraocular reservoir, internal approach, into the subconjunctival space; each additional device. (List separately in addition to code for primary procedure.)

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. The coding information contained herein is gathered from various resources and is subject to change. This document is intended for reference only. Nothing in this document is intended to serve as reimbursement advice, a guarantee of coverage, or a guarantee of payment for the XEN® Gel Stent procedure. Third-party payment for medical products and services is affected by numerous factors. Please refer to your Medicare policy/other payer policies for specific guidance.

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.

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Coding for the XEN® Gel Stent Procedure and Device (continued)

DEVICE CODING

Medicare HOPD

On hospital claims submitted to Medicare, a device Healthcare Common Procedure Coding System (HCPCS) code will need to be reported to include the associated charges for the XEN® Gel Stent 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® Gel Stent 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. 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.

HCPCS CODE	DESCRIPTION
C1783	Ocular implant, aqueous drainage assist device

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® Gel Stent. ASCs should include the charges associated with the device in the total charges for the procedure (*CPT*® code 0449T).

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® Gel Stent 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.

HCPCS CODE	DESCRIPTION
L8612	Ocular implant, aqueous drainage assist device

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 more specific guidance.*

*Remember, *ICD-10-CM* codes submitted to the payer must accurately describe the diagnosis for which the patient receives the XEN® Gel Stent 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.

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Coding for the XEN® Gel Stent 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.

MODIFIER	DESCRIPTION	DEFINITION
RT	Right side	Right side (used to identify procedures performed on the right side of the body)
LT	Left side	Left side (used to identify procedures performed on the left side of the body)

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.

MODIFIER	DESCRIPTION	DEFINITION
51	Multiple procedures	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).*

*This modifier should not be appended to designated "add-on" codes (eg, 0450T).

Coding for the XEN® Gel Stent Procedure and Device (continued)

Modifiers for Discontinued Procedures

In the unforeseen event that the XEN® Gel Stent 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.

MODIFIER	DESCRIPTION	DEFINITION
53	Discontinued procedure	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.
73	Discontinued outpatient hospital/ASC procedure prior to the administration of anesthesia	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).
74	Discontinued outpatient hospital/ASC procedure after administration of anesthesia	Used by the facility to indicate that a surgical or diagnostic procedure requiring anesthesia was terminated due to extenuating circumstances or that it threatened the well-being of the patient after the induction of anesthesia or after the procedure was started.

REVENUE CODES

Revenue codes are used on the HOPD UB-04 (CMS-1450) claim form. 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.

REVENUE CODE	DESCRIPTION
274	Medical/surgical supplies and devices, prosthetic/orthotic devices
278	Medical/surgical supplies and devices, other implants
360	Operating room services, general
490	Ambulatory surgical care, general

IMPORTANT SAFETY INFORMATION (continued)

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Reimbursement for the XEN® Gel Stent Procedure

After submitting a claim to an insurance company, healthcare providers are reimbursed for the episode of care so long as the services are considered medically reasonable and necessary. Outpatient surgeries such as the XEN® Gel Stent 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 center (CMS-1500 claim form)
- Hospital outpatient departments (UB-04 CMS-1450 claim form)

Physician Resources (Resources Used in Episode of Care)

- Physicians (CMS-1500 claim form)

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 Surgery Center Payment System, and HOPDs are paid through the Outpatient Prospective Payment System (OPPS).

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%).

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