THE GENVISC* 850 REIMBURSEMENT GUIDE

Reimbursement Code
J7320

GenVisc*850

5 injection hyaluronic acid regimen

In a field where hyaluronic acids are often considered to be the same, GenVisc*850 is different because it has a unique reimbursement code and provides regimen options for healthcare professionals to decide what's best for each individual patient. It's you, after all, that makes GenVisc*850 work.

Flexible Dosing

Approved for 5 injections, but some patients may benefit from as few as 3 injections.

Reimbursement Code J7320

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INTRODUCTION

Description and Indication

GenVisc*850 is a sterile, viscoelastic non-pyrogenic solution of purified, high molecular weight sodium hyaluronate (average of 850,000 daltons and a range of 620,000 – 1,170,000 daltons) having a pH of 6.8-7.8. Each 2.5 mL of GenVisc*850 contains 10mg/mL of sodium hyaluronate dissolved in a physiological saline (1.0% solution). The sodium hyaluronate is derived from bacterial fermentation. Sodium hyaluronate is a poly-saccharide containing repeating disaccharide units of glucuronic acid and N-acetylglucosamine. GenVisc*850 is indicated for the treatment of pain in osteoarthritis (OA) of the knee in patients who have failed to respond adequately to conservative non-pharmacologic therapy and simple analgesics, e.g., acetaminophen.

Directions for Use

GenVisc*850 is administered by intra-articular injection of the knee. A treatment cycle consists of five injections, given at weekly intervals. Some patients may experience benefit with three (3) injections give at weekly intervals. Injection of subcutaneous lidocaine, or similar local anesthetic, may be recommended prior to injection of GenVisc*850.

Please see full Prescribing Information for additional details.

Using the GenVisc*850 Reimbursement Guide

The GenVisc*850 Reimbursement Guide is intended to provide current and available reimbursement information related to GenVisc*850 in the physician's office and hospital outpatient settings of care when GenVisc*850 is administered as prescribed by a healthcare professional. In this document, coverage, coding, and payment for GenVisc*850 are reviewed for public (Medicare/Medicaid) and private payers. In addition, the reimbursement support available through The Reimbursement Navigator are described. Lastly, reimbursement support tools such as sample claim forms and checklists are provided to assist healthcare providers and staff when utilizing GenVisc*850 for patient therapy.

GenVisc*850

5 injection hyaluronic acid regimen

GenVisc*850 Reimbursement Guide

IMPORTANT SAFETY INFORMATION

- GenVisc*850 is indicated for the treatment of pain in osteoarthritis (OA) of the knee in patients who have failed to respond adequately to conservative non-pharmacologic therapy and to simple analgesics (eg, acetaminophen)

- GenVisc*850 is contraindicated in patients with known hypersensitivity to hyaluronate preparations. Intra-articular injections are contraindicated in cases of present infections or skin diseases in the area of the injection site to reduce the potential for developing septic arthritis

- The effectiveness of a single treatment cycle of less than 3 injections has not been established

- In a clinical trial of 297 patients, the frequency of adverse events in the first treatment cycle was 2.9%, which was identical to the frequency in the saline-control group

- The most commonly reported adverse events in the GenVisc*850 group included: injection site pain (6), allergic reaction (3), arthralgia (2), and bleeding at the injection site (2)

- In a clinical study of 513 completed GenVisc*850 treatment cycles, and a total of 487 completed PBS treatment cycles, the frequency of adverse events between the groups was the same, and did not increase over the course of the three (3) retreatment cycles

Please see full Prescribing Information for more details.

The Reimbursement Navigator
866-556-2259
Fax: 866-377-2244

The Reimbursement Navigator does not file claims or appeal claims for callers, nor can it guarantee that you will be successful in obtaining reimbursement. Third-party payment for medical products and services is affected by numerous factors, not all of which can be anticipated or resolved by The Reimbursement Navigator.

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Email: customerservice@orthogenrx.com • Product Code: 50653-0006-01 GenVisc850.com

DISCLAIMER

Information described in the GenVisc*850 Reimbursement Guide is intended solely for use as a resource tool to assist physician office and hospital outpatient billing staff regarding reimbursement issues. Any determination regarding if and how to seek reimbursement should be made only by the appropriate members of the physician office or hospital outpatient staff, in consultation with the physician, and in consideration of the procedure performed or therapy provided to a specific patient. Avanos does not recommend or endorse the use of any particular diagnosis or procedure code(s) and makes no determination if or how reimbursement may be available. Of important note, reimbursement codes and payment, as well as health policy and legislation, are subject to continual change; information contained in this version of the GenVisc*850 Reimbursement Guide is current.

Avanos cannot be responsible for failure of a physician to obtain reimbursement. Information contained in the GenVisc*850 Reimbursement Guide is for your guidance only. The Reimbursement Navigator does not file or appeal claims for callers, nor can it guarantee reimbursement by third-party payers. For details on the specific services provided by The Reimbursement Navigator, please see the final section of the GenVisc*850 Reimbursement Guide.

Reimbursement specialists at The Reimbursement Navigator are available to assist you with questions related to reimbursement support and access services for therapy with GenVisc*850. To contact a reimbursement specialist, please call 866-556-2259, Monday to Friday from 9:00 am to 8:00 pm EST.

GenVisc*850 Reimbursement Guide

BASICS OF REIMBURSEMENT

Healthcare reimbursement for medical products and services is composed of the following three (3) main elements:

Coverage

Coverage is a payer's determination that healthcare medications and services are medically necessary for a patient and may be included under that patient's specific insurance plan. Most payers cover therapies and their associated administration services if the product will be reimbursed for use in OA of the knee. Typically, coverage is provided under two (2) benefit structures: the medical benefit and/or the pharmacy benefit. Both public and private payers use either medical or pharmacy benefit structures, or both.

Coding

Coding allows healthcare providers and payers to communicate by translating medical terminology into defined units that may be reported for appropriate reimbursement. Providers identify diseases, procedures, drugs, devices, and other healthcare-related items provided to patients through various coding systems. Payers use the same coding systems to form coverage policies and calculate payment for healthcare services.

Major Coding Systems – Physician office or hospital outpatient

Healthcare Common Procedure Coding System (HCPCS) Level II Codes	Alpha-numeric coding systems are used to report specific drugs, supplies, and other healthcare equipment used during the course of medical therapy
International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) Diagnosis Codes	Alpha-numeric codes are used to report patient conditions, illnesses, or symptoms, which support medical necessity for need of healthcare services
Current Procedural Terminology (CPT) Codes (HCPCS Level I Codes)	A numeric coding system is used to report medical services and procedures related to the administration of a drug/product as provided by healthcare professionals

Payment

Payment is the reimbursement amount that a payer renders to a healthcare provider for covered therapies and services. Typically, the payment methodology and payment amount vary based on the site of service where the care is provided.

GENVISC*850 PUBLIC AND PRIVATE PAYER COVERAGE INFORMATION

Coverage: Medicare

Medicare is a federally funded health insurance program that was established as part of the Social Security Act of 1965. It provides coverage to almost 50 million beneficiaries, and is administered through the following 4 benefit categories:

Part A
Hospital Insurance

Pays for inpatient hospital, skilled nursing facility, hospice, and certain home healthcare services; drugs, devices, and biologics are included within payment for Part A services when provided at covered facilities.

Part B
Medical Insurance

Covers physician-administered drugs and patient visits to physician office and hospital outpatient settings.

Part C
Medicare Advantage

Administered by managed care plans, which are accountable for providing traditional Medicare services/benefits; however they have flexibility to offer additional benefits.

Part D
Medicare Prescription Drug Coverage

Covers oral or self-administered drugs, is offered through two benefit structures, and administered by private organizations.

Medicare will reimburse healthcare providers for GenVisc*850 when provided to a patient as a medically necessary therapy in the physician office when local carrier guidelines are followed. Because GenVisc*850 is a physician-administered product, it is covered under Medicare Part B, and may be covered under Part C subject to commercial plan Medicare policies.

For products that are covered under Medicare Part B, coverage decisions are typically made through Local Coverage Determinations (LCDs). Medicare Administrative Contractors (MACs) generally develop LCDs. LCDs are specific to a MAC's jurisdiction, meaning that specific coverage criteria for a product and its administration, as well as coding requirements, may vary by Medicare contractor.

Please consult your Medicare contractor to determine if any local coverage policies apply to GenVisc*850. To verify a patient's Medicare benefits and coverage information, please call **The Reimbursement Navigator** at Phone: **866-556-2259**, Monday to Friday from 9:00 am to 8:00 pm EST.

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GENVISC*850 PUBLIC AND PRIVATE PAYER COVERAGE INFORMATION

Coverage: Private Payers

Each private payer plan administers its own benefits and determines specific coverage and payment policies. Some private payers may follow Medicare's coverage policies, while other private payers may have more restrictive or less restrictive benefits. Typically, private payers will cover GenVisc*850 when used for its FDA-approved indication. Private payers may implement restrictions, such as requiring prior authorization and/or other utilization controls. Coverage may also vary significantly by the specific contracts that are negotiated between providers and private payers. Requesting plan-specific coverage information on GenVisc*850 is an important step in understanding your patients' benefits, especially since private payer plans vary considerably.

To verify a patient's private payer plan benefits and coverage information, please call **The Reimbursement Navigator** at **866-556-2259** Monday to Friday, from 9:00 am to 8:00 pm EST.

Coverage: Medicaid

Each state administers its own Medicaid program; therefore, GenVisc*850 coverage may vary from state to state. For updates on the status of Medicaid coverage for GenVisc*850 please call **The Reimbursement Navigator** at **866-556-2259** Monday to Friday, from 9:00 am to 8:00 pm EST.

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Email: customerservice@orthogenrx.com ● Product Code: 50653-0006-01 GenVisc850.com

GENVISC*850 REIMBURSEMENT IN THE PHYSICIAN OFFICE SETTING

Coding

The codes relevant to GenVisc*850 and its administration in the physician office setting are described in the following section. For more information on reporting various codes in the physician office site of care, please refer to the sample CMS-1500 claim form for GenVisc*850 therapy on page 13.

Note: While the general codes relevant to GenVisc*850 therapy in the physician office setting are noted in this section, other codes beyond those listed here may also be considered appropriate. As coverage for codes may vary by payer, please call **The Reimbursement Navigator** at **866-556-2259**, Monday to Friday from 9:00 am to 8:00 pm EST for assistance to verify specific or unique payer coding requirements.

GENVISC*850 REIMBURSEMENT IN THE PHYSICIAN OFFICE SETTING

ICD-10-CM

The ICD-10-CM diagnosis codes listed below may be appropriate to report for patients with OA of the knee and who are prescribed and administered GenVisc*850 therapy in the physician office setting.

ICD-10-CM	Description
M17.0	Bilateral primary osteoarthritis of knee
M17.10	Unilateral primary osteoarthritis, unspecified knee
M17.11	Unilateral primary osteoarthritis, right knee
M17.12	Unilateral primary osteoarthritis, left knee
M17.2	Bilateral post-traumatic osteoarthritis of knee
M17.30	Unilateral post-traumatic osteoarthritis, unspecified knee
M17.31	Unilateral post-traumatic osteoarthritis, right knee
M17.32	Unilateral post-traumatic osteoarthritis, left knee
M17.4	Other bilateral secondary osteoarthritis of knee
M17.5	Other unilateral secondary osteoarthritis of knee
M17.9	Osteoarthritis of knee, unspecified

On a CMS-1500 claim form, applicable ICD-10-CM diagnosis codes must be reported in Box 21. Several of the above coding systems apply to other settings of care (eg, hospital inpatient, home health, pharmacy, etc.) beyond those noted above; only sites of service relevant to GenVisc*850 and its administration are outlined here.

GENVISC*850 REIMBURSEMENT IN THE PHYSICIAN OFFICE SETTING

HCPCS

To report the use of GenVisc*850 in the physician office, use of GenVisc*850's HCPCS code is appropriate, as noted below:

HCPCS Code	Description
J7320	Hyaluronan or derivative, GenVisc*850 for intra-articular injection, 1 mg

On a CMS-1500 claim form, Box 24D should be used for reporting the GenVisc 850 HCPCS code and appropriate modifiers

CPT

To report the physician administration of GenVisc*850, the following CPT codes may be appropriate when GenVisc*850 is administered in the physician office setting:

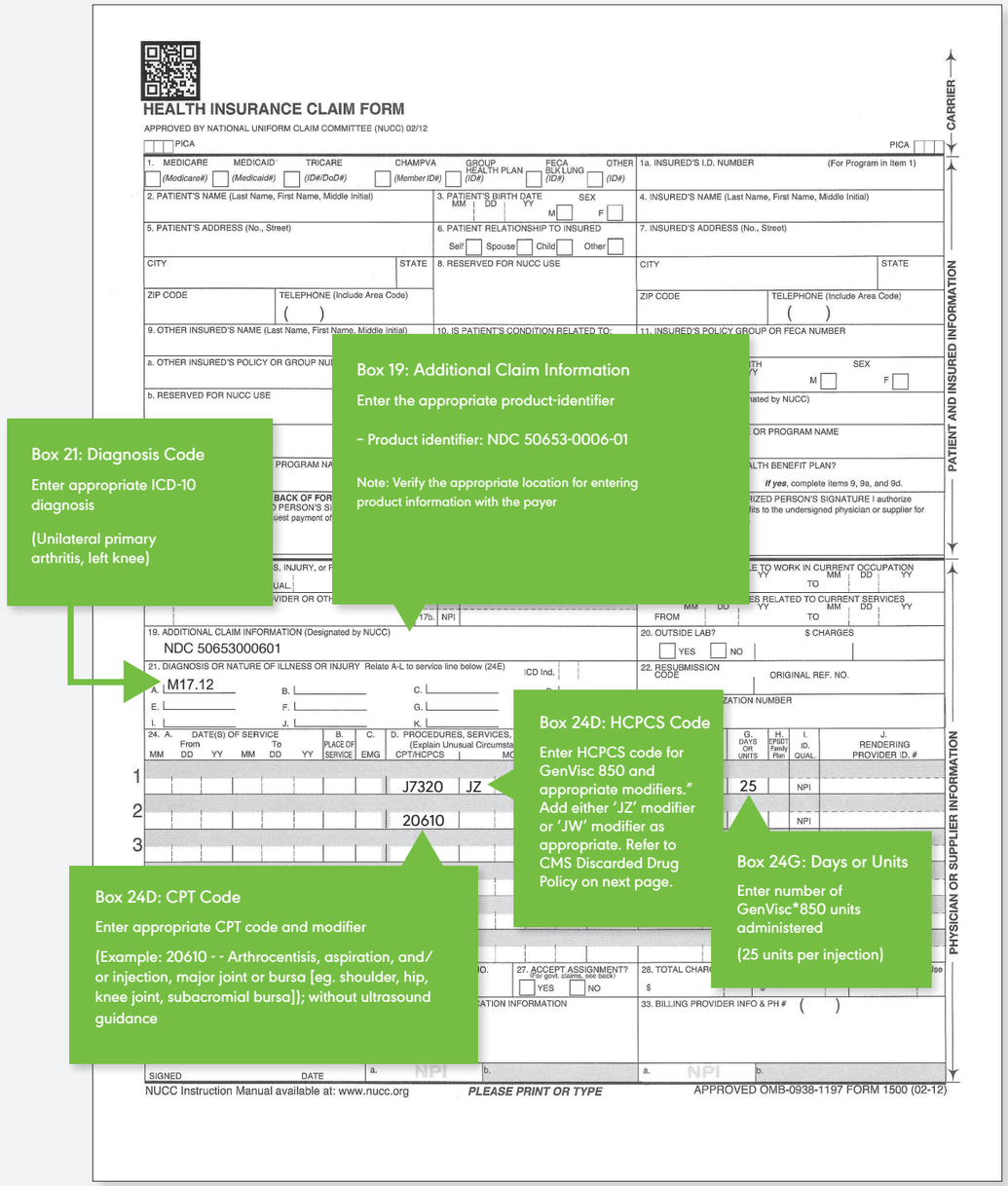
CPT	Description
20610	Arthrocentesis, aspiration, and/or injection; major joint or bursa (eg, shoulder, hip, knee joint, subacromial bursa); without ultrasound guidance
20611	Arthocentesis, aspiration, and/or injection; major joint or bursa (eg, shoulder, hip, knee joint, subacromial bursa); with ultrasound guidance, with permanent recording and reporting

Providers are responsible for the selection of appropriate codes depending on clinical diagnosis. Information in the above table provides a general framework for understanding possible coding alternatives. It should not be used as a substitute for a healthcare professional's own judgment.

CPT codes should be reported in Box 24D of the CMS-1500 claim form as well. In certain instances, payers may require modifier "-RT" (right side) or "-LT" (left side) to be documented after CPT code 20610, to specify which knee was injected with GenVisc*850. For bilateral administration of GenVisc*850, some payers may require modifier "-50" (bilateral procedure) to be documented after CPT code 20610 or 20611.

NDC Number: Because GenVisc*850, and all other hyaluronic acid (HA)/Viscosupplement products, are regulated as medical devices, they are not assigned NDC numbers. Instead the product code serves a similar purpose for devices as the NDC code serves for pharmaceuticals and can be used as an NDC proxy. **The number for GenVisc*850 is 50653-0006-01.**

GENVISC*850 CMS-1500 SAMPLE CLAIM FORM



POLICY

CMS Discarded Drug Policy
Medicare contractors now require the modifier JW to identify unused product from single-use syringes that are appropriately discarded, or JZ to identify situations where there is no left over HA.

The JZ modifier is billed on the same claim line as the GenVisc* HCPCS code in box 24D in the modifier section.
This MUST be included if there is no product discarded or your Medicare claim may be denied.

The JW modifier, billed on a separate claim line, supports payment for the amount of discarded HA. For example, a single-use syringe that is labeled to contain 25 units of a HA has 22 units administered to the patient and 3 units discarded. The 22-unit dose is billed on one line (Box 24G), while the discarded 3 units is billed on another line (Box 24G) accompanied by the JW modifier. Calculate and include the appropriate charge amount for both the HA administered and discarded on the appropriate line in Box 24F. In the above example 88% of the charge for HA administered and 12% for HA discarded. Both line items will be processed for payment. Providers must also record the discarded amounts of drugs and biologics in the patient's medical record. With GenVisc* 850, it's unlikely that there will be many occasions where there is discarded product so the JW modifier may only be needed from time to time.

24. A. DATE(S) OF SERVICE From MM	DD	YY	To MM	DD	YY	B. PLACE OF SERVICE	C. EMG	D. PROCEDURES, SERVICES, OR SUPPLIES (Explain Unusual Circumstances) CPT/HCPCS	MODIFIER	E. DIAGNOSIS POINTER	F. $ CHARGES	G. DAYS OR UNITS	H. EPSDT Family Plan	I. ID. QUAL.	J. RENDERING PROVIDER ID. #
08	24	XX	08	24	XX			20610						NPI	
08	24	XX	08	24	XX			J7320			See instructions	22		NPI	
08	24	XX	08	24	XX			J7320	JW		See instructions	3		NPI	

For more information on the JZ and JW modifiers, please review the Q&A from CMS found at: jw-modifier-faqs.pdf (cms.gov)

GenVisc*850 Reimbursement Guide

PAYMENT

Medicare

HCPCS Code	Description	Allowed Payment Rate
J7320	Hyaluronan or derivative, GenVisc*850 for intra-articular injection, 1 mg	Published reimbursement allowable from the Medicare ASP fee schedule published each calendar quarter.

CPT	Description	2023 Medicare National Average Payment
20610	Arthrocentesis, aspiration, and/or injection; major joint or bursa (eg, shoulder, hip, knee joint, subacromial bursa); without ultrasound guidance	$73.21
20611	Arthocentesis, aspiration, and/or injection; major joint or bursa (eg, shoulder, hip, knee joint, subacromial bursa); with ultrasound guidance, with permanent recording and reporting	$113.65

Providers are responsible for the selection of appropriate codes depending on clinical diagnosis. Information in the above table provides a general framework for understanding possible coding alternatives. It should not be used as a substitute for a healthcare professional's own judgment.

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PAYMENT

Private Payers

Private payers typically negotiate payment rates for GenVisc*850. When administered in the physician office setting, payment may be based on a fee schedule, a percentage of billed or allowable charges, or a percentage of Average Wholesale Price (AWP), Wholesale Acquisition Cost (WAC) or ASP. For each patient, cost-sharing requirements, such as coinsurance, co-payments, and annual deductible amounts, will vary by individual insurance plan.

Medicaid

Each state administers its own Medicaid program therefore GenVisc*850 coverage may vary from state to state. In addition, you should confirm whether Medicaid patients have other forms of insurance. Medicaid is the payer of last resort, so in cases where patients have Medicare or other types of supplemental commercial insurance, Medicaid always pays secondary or tertiary to these payers. For updates on the status of Medicaid coverage for GenVisc*850 please call **The Reimbursement Navigator** at **866-556-2259**, Monday to Friday, from 9:00 am to 8:00 pm EST for assistance to verify specific or unique payer coding requirements.

GenVisc*850 Reimbursement Guide

GENVISC*850 REIMBURSEMENT SUPPORT

The Reimbursement Navigator

The Reimbursement Navigator is a comprehensive reimbursement support program and is available to provide support to your site of service for GenVisc*850 reimbursement and access challenges.

The Reimbursement Navigator assists patients and healthcare providers by offering the following reimbursement and access services:

- Verifying patient-specific insurance benefits
- Navigating prior authorization processes
- Conducting payer criteria research
- Identifying sources of alternate coverage
- Coding/billing and claims submission support
- Strategies to appeal denied claims

The Reimbursement Navigator
866-556-2259
Fax: 866-377-2244
orthogenrx.aspnprograms.com

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BENEFIT VERICATIONS AND PRIOR AUTHORIZATION CHECKLIST

Insurance benefit verifications are recommended prior to the initiation of a patient's treatment in order to better understand his or her specific health plan benefits, and any requirements the plan may have for GenVisc*850 coverage and claims submission. Reimbursement specialists at **The Reimbursement Navigator** can provide support in conducting patient-specific benefit verifications and assisting with prior authorization processes. Below is a list of information that is typically obtained through this process.

- ◯ Does the patient's insurance plan cover GenVisc*850 under a medical benefit or pharmacy benefit?
- ◯ Does the patient's insurance plan require prior authorization for GenVisc*850?
  - What information does the patient insurance plan need for the prior authorization request?
  - How long will the prior authorization process take?
  - Once obtained, how long will the prior authorization last before another one is required?
- ◯ What are the patient's cost-sharing responsibilities?
  - What is the patient's annual deductible? If the deductible has not yet been met in full, how much is left?
  - What is the patient's maximum out-of-pocket requirement? If the maximum out-of-pocket has not yet been met in full, how much is left?
  - What is the patient's coinsurance or co-payment for GenVisc*850 administration?
- ◯ Does the patient have other insurance coverage that needs to be coordinated with the primary source?
- ◯ Does the patient's insurance plan have any coding or claims submission guidelines that must be followed for reporting GenVisc*850 and its administration?

For any questions you may have related to patient benefit verifications and prior authorization processes, please call **The Reimbursement Navigator** at **866-556-2259**, Monday to Friday, from 9:00 am to 8:00 pm EST.

DENIED CLAIMS AND APPEALS CHECKLIST

If a claim for GenVisc*850 is denied, consider the following general guidelines regarding how to review the denial, resubmit the claim form, and appeal the denial.

Review the Denial

- Review the Explanation Of Benefits (EOB) sent by the patient's payer to identify why the claim was denied:
  - Claims often are denied as a result of simple errors, such as missing identification numbers, patient names, or signatures; claim errors may also consist of reporting incorrect codes or modifiers
- Resubmit the corrected claim form immediately after addressing any errors.

Resubmitting the Claim Form

- If the reason for denial was not a result of claim submission errors, then submit a letter of medical necessity and supportive materials/literature that highlight the following:
  - Patient's medical history
  - Other therapies that have been tried or were contraindicated
  - Medical reasons this patient was prescribed GenVisc*850
  - Medical risks due to delay of treatment

Appeal the Denial

- If the patient's payer denies the claim again, then consider filing a grievance and reviewing the appeals process; filing a grievance or an appeal must be done as soon as possible to avoid any time frame limitations
- Monitor payer response to appealing the denied claim and determine if continued action is necessary
- Patients or their representatives may decide to become involved in the appeals process

To verify a patient's insurance benefits and coverage information, please call **The Reimbursement Navigator** at **866-556-2259**, Monday to Friday, from 9:00 am to 8:00 pm EST, or Fax to 866-377-2244. Enroll online at orthogenrx.aspnprograms.com

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