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Active Healing Through Orthobiologics

The Power of Choice.

Reimbursement Guide for the Bioventus Hyaluronic Acid (HA) Portfolio

DUROLANE®
hyaluronic acid, stabilized single injection

GELSYN-3®
3 injection hyaluronic acid treatment

SUPARTZ FX®
sodium hyaluronate

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Introduction

Bioventus LLC has developed this resource to support healthcare professionals (HCPS) navigate coverage, coding, and reimbursement for the Bioventus portfolio of hyaluronic acid (HA) products: DUROLANE, GELSYN-3, and SUPARTZ FX.

Understanding coverage, coding, and reimbursement is critical for ensuring patient access and successful claims adjudication.

The information in this Bioventus Reimbursement Guide is intended solely as a resource to assist the staff in physicians' offices and hospitals with certain reimbursement-related questions. Bioventus makes no representation about the information provided, as reimbursement information, including applicable policies and laws, are subject to change without notice from Bioventus. This Reimbursement Guide is not conclusive or exhaustive and is not intended to replace the guidance of a qualified, professional advisor. The appropriate staff member of a physician's office or hospital, not Bioventus, determines the appropriate method of seeking reimbursement based on the medical procedure performed and any other relevant information. Bioventus LLC does not recommend or endorse the use of any particular diagnosis or procedure code(s), and makes no determination regarding if or how reimbursement may be available. The use of this information does not guarantee payment or that any payment received will equal a certain amount.

Information about the Healthcare Common Procedure Coding System (HCPCS) codes is based on guidance issued by the Centers for Medicare & Medicaid Services (CMS) applicable to Medicare Part B and may not apply to other public or private payers. Consult the relevant manual and/or other guidelines for a description of each code to determine the appropriateness of a particular code and for information on additional codes.

Summary of Indications for Use

DUROLANE

DUROLANE is indicated for the treatment of pain in osteoarthritis (OA) of the knee in patients who have failed to respond adequately to conservative non-pharmacological therapy or simple analgesics (e.g., acetaminophen).

Do not inject DUROLANE in patients with knee joint infections, skin diseases, or other infections in the area of the injection site. Do not administer to patients with known hypersensitivity or allergy to sodium hyaluronate preparations. Risks can include transient pain or swelling at the injection site. DUROLANE has not been tested in pregnant or lactating women or in children.

Full prescribing information can be found in product labeling at www.DUROLANE.com or by contacting Bioventus Customer Service at 1-800-836-4080.

GELSYN-3

GELSYN-3 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). Do not administer to patients with known hypersensitivity (allergy) to sodium hyaluronate preparations. Do not inject GELSYN-3 into the knees of patients having knee joint infections or skin diseases or infections in the area of the injection site.

GELSYN-3 is not approved for pregnant or nursing women or for children. Risks can include general knee pain and warmth and redness or pain at the injection site.

Full prescribing information can be found in product labeling at www.GELSYN3.com or by contacting Bioventus Customer Service at 1-800-836-4080.

SUPARTZ FX

SUPARTZ FX is indicated for 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).

You should not use SUPARTZ FX if your patient has infections or skin diseases at the injection site or allergies to avian (bird) products (feathers and eggs). SUPARTZ FX is not approved for pregnant or nursing women or for children.

Risks can include general knee pain and warmth and redness or pain at the injection site.

Full prescribing information can be found at www.SUPARTZFX.com or by contacting Bioventus Customer Service at 1-800-836-4080.

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Coverage and Reimbursement for HA Products

MEDICARE[1]

Medicare is the federal health insurance program that covers individuals 65 years of age and older, qualified disabled, and those diagnosed with end-stage renal disease. In general, Medicare covers hospital inpatient services under Medicare Part A and services performed in the outpatient and physician office setting under Medicare Part B. Medicare Part D covers outpatient prescription drugs.

There are 2 types of Medicare health plans: fee-for-service (FFS) Medicare, also known as traditional Medicare, which is administered by Medicare Administrative Contractors (MACs); and Medicare Advantage, commonly referred to as Medicare Part C or managed Medicare, which is administered by private commercial plans.

Traditional FFS Medicare

Medicare will reimburse HCPs for HA products when provided to a patient as a "medically reasonable" and necessary therapy when administered and incident to a physician's professional services in the physician office or hospital outpatient care settings. Because HA products must be administered by an HCP, they are a covered benefit under Medicare Part B.[2]

Information on Medicare reimbursement for HA products can be found in the Medicare Claims Processing Manual, Chapter 17 – Drugs and Biologicals, Section 20.1.3.[2]

Medicare pays 80% of an allowable charge and the Medicare beneficiary is responsible for the remaining 20% coinsurance when services are provided in a physician's office and/or hospital outpatient setting. Beneficiaries who purchase a Medigap plan or have other types of secondary insurance may have a portion or all of their coinsurance covered.

HCPs are required to buy and bill HA products under traditional FFS Medicare. There is no option for an HCP to obtain the product from a specialty pharmacy. Under traditional FFS Medicare, there are no prior authorization requirements; however, some MACs could have other prescribing guidelines or restrictions outlined in a Local Coverage Determination (LCD).

Medicare Advantage

Medicare Advantage, commonly referred to as "managed Medicare," must include all covered benefits under traditional FFS Medicare Parts A and B. Many commercial payers that offer a Medicare Advantage plan may include extra benefits, like vision, hearing, dental, and/or health and wellness programs. However, unlike traditional Medicare, restrictions such as prior authorizations or step therapy may apply and should be verified by the HCP before injecting the patient with a Bioventus HA product.

MEDICAID[1]

Medicaid is a public health insurance program jointly funded by federal and state governments. Medicaid that is administered directly by the state is commonly referred to as “FFS Medicaid”; when administered by a commercial managed care plan, it is commonly referred to as “managed Medicaid.” Some states may be all FFS or all managed Medicaid, whereas some states may have a combination of both FFS and managed Medicaid enrollment.

Medicaid covers individuals with very limited income and resources, who are required to meet specific poverty guidelines set by individual states. Medicaid recipients who are eligible for both Medicare and Medicaid are referred to as “dual-eligible recipients.” For these Medicaid recipients, Medicare is the primary payer and Medicaid is the secondary payer.

Dual-eligible recipients include patients who are receiving full Medicaid and Medicare benefits and those patients who are enrolled in the Medicare Savings Program (MSP). There are different levels of subsidies available through the MSP, and HCPs should check with the MSP in their state to determine a patient’s level of eligibility for assistance. For more information on the subsidy levels, please visit www.medicare.gov.

Prior authorization may be required for products under FFS and/or managed Medicaid. Some managed Medicaid plans may allow the physician to obtain HA products from a specialty pharmacy.

Access and reimbursement for HA products will vary by state and by managed Medicaid plans. Many states will publish a fee schedule for physician-administered drugs and may include HA products.

Cost-sharing under Medicaid can vary by state and managed care plan, but patients typically have little or no cost share for healthcare services. It is important for all HCPs to check with the recipient’s respective Medicaid state or managed care plan before administering, treatment to determine if any of the Bioventus HA products are covered and at what reimbursement formula.

COMMERCIAL PLANS

Commercial insurance plan options include non-government, employer-sponsored health plans and coverage purchased through a state or federally run health insurance exchange. These plans have various benefit designs and coverage restrictions, and physician reimbursement will be based on contracted rates between the commercial plan and the HCP.

Most commercial insurance plans cover physician-administered, medically necessary drugs and related drug administration services. Prior authorization may also be required by some payers. Commercial plans may allow or require the physician to obtain HA products from a specialty pharmacy. Patient copayment, coinsurance, and deductible requirements can vary dramatically by plan.

It is always advisable to verify the patient’s healthcare benefits and determine if there are any plan-specific requirements before treating them with a Bioventus HA product.

Healthcare Provider Support:
BV360 Reimbursement Solution

BV360 is a comprehensive solution to navigate the reimbursement landscape and help your patients gain access to DUROLANE, GELSYN-3, and SUPARTZ FX.

Contact the BV360 team of experts for help with the following:

Medical and pharmacy benefit investigations for DUROLANE, GELSYN-3, and SUPARTZ FX

- Completion of benefit determinations within 24 hours
- Identification of insurance coverage, out-of-pocket costs, and means of fulfillment

- Determination of prior authorization requirements and forms
- Transcription of prior authorization forms
- Tracking and follow-up until final outcome
- HCP access to LMN template

- Support with appeals and denials, from start to finish

- Triage prescription to specialty pharmacy and track status, from start to finish

- Field Reimbursement Managers to provide assistance with patient-specific reimbursement issues.

Visit **MyBV360.com**

Fax a completed Benefits Request Form to **1-833-MyBVFAX (1-833-692-8329)**

Call **1-833-MyBV360 (1-833-692-8360)** Monday-Friday, 9 AM to 7 PM ET

Coding Information

HEALTHCARE COMMON PROCEDURE CODING SYSTEM (HCPCS) CODES

Claims for physician-administered drugs or devices billed under the medical benefit must be submitted with an HCPCS code to identify the drug or device administered to the patient.

DUROLANE, GELSYN-3 and SUPARTZ FX have been issued permanent HCPCS codes and these should be used accordingly when submitting a claim to payers.

HCPCS Code[3]	Descriptor	Units
J7318	Hyaluronan or derivative, DUROLANE, for intra-articular injection, per 1 mg	DUROLANE 20 mg/mL is reported as **J7318 with 60 units**
J7328	Hyaluronan or derivative, GELSYN-3, for intra-articular injection, 0.1 mg	GELSYN-3 16.8 mg/2 mL is reported as **J7328 with 168 units**
J7321	Hyaluronan or derivative, Hyalgan or SUPARTZ FX, for intra-articular injection, per dose	SUPARTZ FX 25 mg/2.5 mL is reported as **J7321 with 1 unit**

NATIONAL DRUG CODES (NDCs)[4,5]

The United States Food and Drug Administration (FDA) lists NDCs in a 10-digit format, but payers often require an 11-digit NDC in a 5-4-2 format for electronic claims forms. Guidelines for reporting the NDC in the appropriate format, quantity, and unit of measure, as well as the location on the claim form, may vary by payer. **HCPs should review payer-specific requirements prior to submitting a claim.**

	Strength	FDA-listed 11-digit NDC (5-4-2 format)*
DUROLANE	20 mg/mL (supplied in a 3 mL single-use syringe)	89130-2020-01
GELSYN-3	8.4 mg/mL (supplied in a 2 mL single-use syringe)	89130-3111-01
SUPARTZ FX	10 mg/mL (supplied in a 2.5 mL single-use syringe)	89130-4444-01

*Certain payers will require the NDC without the dashes between the number segments.

CURRENT PROCEDURAL TERMINOLOGY (CPT) CODES

Injection Services

To report the injection of DUROLANE, GELSYN-3, or SUPARTZ FX that has been administered with direct physician or other qualified HCP supervision, it may be appropriate to use the following CPT codes and appropriate modifiers.

CPT Code[6]	Description
20610	Arthrocentesis, aspiration and/or injection, major joint or bursa (e.g., shoulder, hip, knee, subacromial bursa); without ultrasound guidance
20611*	Arthrocentesis, aspiration and/or injection, major joint or bursa (e.g., shoulder, hip, knee, subacromial bursa); with ultrasound guidance, with permanent recording and reporting

*Verify that the use of ultrasound guidance is covered by the plan.

Modifier	Description
LT	Left side (anatomic modifier indicating the material was injected into the left knee)
RT	Right side (anatomic modifier indicating the material was injected into the right knee)
50	Bilateral procedure (anatomic modifier indicating the material was injected into both knees)

Physician Services

If the patient has an office visit on the same day as an injection of DUROLANE, GELSYN-3, or SUPARTZ FX, the HCP may be able to bill an evaluation and management (E&M) code. Typically, a distinct, separately identifiable service for the injection must be documented in the patient's medical record to bill for these services.

CPT Code[6]	Description
99201	New patient visit, level 1
99202	New patient visit, level 2
99203	New patient visit, level 3
99204	New patient visit, level 4
99205	New patient visit, level 5
99212	Established patient visit, level 2
99213	Established patient visit, level 3
99214	Established patient visit, level 4
99215	Established patient visit, level 5

When one of these E&M CPT codes is used, a CPT modifier may be appended to the E&M code to indicate other billable services that were also provided.

Modifiers	Description
25	Significantly and separately identifiable E&M service (indicates that on the day of the injection[s], a significantly and separately identifiable E&M service over and above the injection[s] was provided)
57	Decision for surgery (indicates an E&M service that resulted in the initial determination to inject the material into the knee[s])

DIAGNOSIS CODES

Applicable International Classification of Diseases, 10th Revision, Clinical Modification (ICD-10-CM) codes are listed in the table below.

ICD-10-CM[7] (Unilateral)	Description
M17.10	Unilateral primary osteoarthritis, unspecified knee
M17.11	Unilateral primary osteoarthritis of knee, right knee
M17.12	Unilateral primary osteoarthritis of knee, left knee
M17.30	Unilateral post-traumatic osteoarthritis, unspecified knee
M17.31	Unilateral post-traumatic osteoarthritis of knee, right knee
M17.32	Unilateral post-traumatic osteoarthritis of knee, left knee
M17.5	Other unilateral secondary osteoarthritis of knee
M17.9	Osteoarthritis of knee, unspecified

ICD-10-CM[7] (Bilateral)	Description
M17.0	Bilateral primary osteoarthritis of knee
M17.2	Bilateral post-traumatic osteoarthritis of knee
M17.4	Other bilateral secondary osteoarthritis of knee

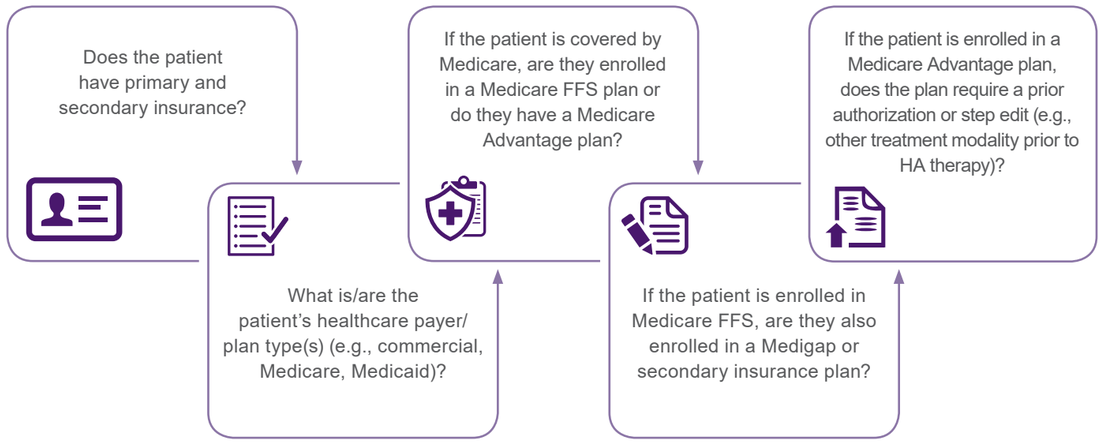
Considerations for Verifying Insurance Benefits

It is important to understand and verify patient insurance benefits prior to initiating treatment. Conducting a benefit verification can provide the HCP office with the following:

- **Payer coverage requirements**
- **Coding and billing requirements**
- **Patient cost-share amount**

To support patient access and minimize claims-processing delays, consider the information below prior to treating a patient and submitting a claim.

- **What is the patient's insurance coverage status?**

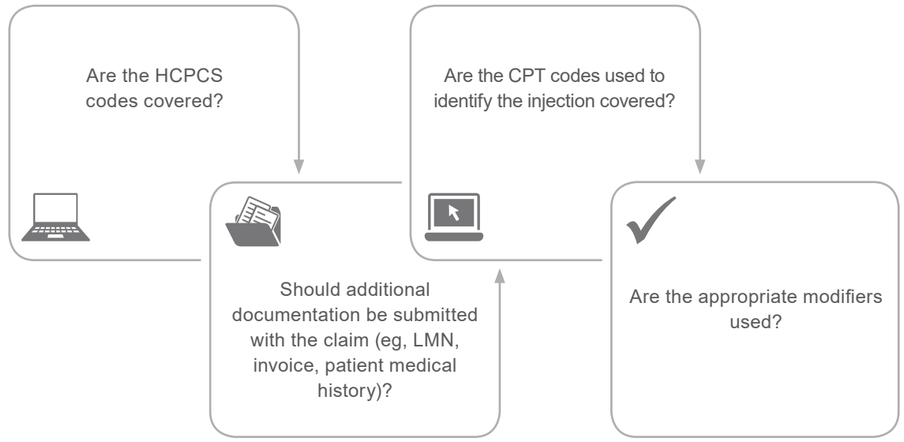


BV360 Reimbursement Solution is available to support HCPs with verifying insurance benefits for DUROLANE, GESLYN-3 and SUPARTZ FX.

Visit **MyBV360.com** or call BV360 at **1-833-MyBV360**.

- **Does the payer provide coverage for HA products?**

DUROLANE (J7318), GELSYN-3 (J7328) AND SUPARTZ FX (J7321)



- **What is the patient's cost-share for both the product and its administration (i.e., deductible, copay, coinsurance, out-of-pocket maximum)?**

- **Are there any access restrictions, such as mandatory buy-and-bill or specialty pharmacy access?**

Sample CMS-1500 Claim Forms for Physician Office

DUROLANE SAMPLE CLAIM FOR KNEE JOINT INJECTIONS

Box 21: Diagnosis Code
- Enter the appropriate ICD-10-CM diagnosis code, e.g.:
  - Osteoarthritis, unilateral or bilateral knee, M17.**
  - Asterisks indicate additional digits are required. Final code depends on medical record documentation

Note: Other additional diagnosis codes may apply

Box 24G: Service Units
- Enter the appropriate number of units of service
- Enter 60 in the "units" column for each syringe. Providers must bill 60 units of HCPCS code J7318 for DUROLANE as J7318 reimburses per unit

14. DATE OF CURRENT ILLNESS, INJURY, or PREGNANCY (LMP) MM DD YY — QUAL. — 15. OTHER DATE QUAL. MM DD YY — 16. DATES PATIENT UNABLE TO WORK IN CURRENT OCCUPATION MM DD YY FROM TO

17. NAME OF REFERRING PROVIDER OR OTHER SOURCE — 17a. — 17b. NPI — 18. HOSPITALIZATION DATES RELATED TO CURRENT SERVICES MM DD YY FROM TO

19. ADDITIONAL CLAIM INFORMATION (Designated by NUCC) — 20. OUTSIDE LAB? YES NO $ CHARGES

21. DIAGNOSIS OR NATURE OF ILLNESS OR INJURY Relate A-L to service line below (24E) — ICD Ind. 0 — 22. RESUBMISSION CODE — ORIGINAL REF. NO.

A. M17.** B. C. D. E. F. G. H. I. J. K. L. — 23. PRIOR AUTHORIZATION NUMBER

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. #
1	MM	DD	YY	MM	DD	YY	11		J7318				A		60		NPI	
2	MM	DD	YY	MM	DD	YY	11		2061*	**			A		1		NPI	
3	MM	DD	YY	MM	DD	YY	11		992**	**			A		1		NPI	
4																	NPI	
5																	NPI	

Box 24D: Product/Procedure Code
- Enter the appropriate HCPCS code, e.g., J7318 for DUROLANE
- Enter the appropriate CPT code(s) and modifier(s), e.g.:
  - Administration: 2061* (attach modifier 50 for bilateral injections and modifier LT or RT for unilateral injections)
  - Visit: 992** (attach modifier 25 for a level 1 to 5 physician visit that is separately identifiable from the drug administration service; attach modifier 57 for a decision for surgery on the same day)
  - Asterisks indicate additional digits are required. Final code depends on medical record documentation

Always include valid codes on claims to payers. Contact your provider-relations representative or payer website to confirm requirements.

GELSYN-3 SAMPLE CLAIM FOR KNEE JOINT INJECTIONS

Box 21: Diagnosis Code
- Enter the appropriate ICD-10-CM diagnosis code
- Osteoarthritis, unilateral or bilateral knee, M17.**
- Asterisks indicate additional digits are required. Final code depends on medical record documentation

Note: Other additional diagnosis codes may apply

Box 24G: Service Units
- Enter the appropriate number of units of service
- Enter 168 in the "units" column for each syringe. Providers must bill 168 units of HCPCS code J7328 for the single injection of GELSYN-3, as J7328 reimburses per unit

14. DATE OF CURRENT ILLNESS, INJURY, or PREGNANCY (LMP) MM DD YY — QUAL. — 15. OTHER DATE QUAL. MM DD YY — 16. DATES PATIENT UNABLE TO WORK IN CURRENT OCCUPATION MM DD YY FROM TO

17. NAME OF REFERRING PROVIDER OR OTHER SOURCE — 17a. — 17b. NPI — 18. HOSPITALIZATION DATES RELATED TO CURRENT SERVICES MM DD YY FROM TO

19. ADDITIONAL CLAIM INFORMATION (Designated by NUCC) — 20. OUTSIDE LAB? YES NO $ CHARGES

21. DIAGNOSIS OR NATURE OF ILLNESS OR INJURY Relate A-L to service line below (24E) — ICD Ind. 0 — 22. RESUBMISSION CODE — ORIGINAL REF. NO.

A. M17.** B. C. D. E. F. G. H. I. J. K. L. — 23. PRIOR AUTHORIZATION NUMBER

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. #
1	MM	DD	YY	MM	DD	YY	11		J7328				A		168		NPI	
2	MM	DD	YY	MM	DD	YY	11		2061*	**			A		1		NPI	
3	MM	DD	YY	MM	DD	YY	11		992**	**			A		1		NPI	
4																	NPI	
5																	NPI	

Box 24D: Product/Procedure Code
- Enter the appropriate HCPCS code, e.g.: J7328 for GELSYN-3
- Enter the appropriate CPT code(s) and modifier(s), e.g.:
  - Administration: 2061* (attach modifier 50 for bilateral injections and modifier LT or RT for unilateral injections)
  - Visit: 992** (attach modifier 25 for a level 1 to 5 physician visit that is separately identifiable from the drug administration service; attach modifier 57 for a decision for surgery on the same day)
  - Asterisks indicate additional digits are required. Final code depends on medical record documentation
  - Some payers may require modifier EJ, usually following the first injection, to indicate subsequent injections in a series of injections. Do not use this modifier for the first injection of each series of injections. Injection of the left knee is a separate series from injection of the right knee

For all subsequent injections, submit the appropriate codes based on the services documented in the medical record.

Always include valid codes on claims to payers. Contact your provider-relations representative or payer website to confirm requirements.

SUPARTZ FX SAMPLE CLAIM FOR KNEE JOINT INJECTIONS

Box 21: Diagnosis Code
- Enter the appropriate ICD-10-CM diagnosis code.
  - Osteoarthritis, unilateral or bilateral knee, M17.**
  - Asterisks indicate additional digits are required. Final code depends on medical record documentation

Note: Other additional diagnosis codes may apply

Box 19: Additional Claim Information
- When completing a claim for SUPARTZ FX, add the product name and strength

Box 24G: Service Units
- Enter the appropriate number of units of service

14. DATE OF CURRENT ILLNESS, INJURY, or PREGNANCY (LMP) MM DD YY QUAL. MM DD YY
15. OTHER DATE QUAL. MM DD YY
16. DATES PATIENT UNABLE TO WORK IN CURRENT OCCUPATION MM DD YY FROM MM DD YY TO
17. NAME OF REFERRING PROVIDER OR OTHER SOURCE
17a.
17b. NPI
18. HOSPITALIZATION DATES RELATED TO CURRENT SERVICES MM DD YY FROM MM DD YY TO
19. ADDITIONAL CLAIM INFORMATION (Designated by NUCC): SUPARTZ FX (sodium hyaluronate) 25 mg, NDC 89130444401
20. OUTSIDE LAB? YES NO $ CHARGES
21. DIAGNOSIS OR NATURE OF ILLNESS OR INJURY Relate A-L to service line below (24E) ICD Ind. 0
A. M17.** B. C. D. E. F. G. H. I. J. K. L.
22. RESUBMISSION CODE ORIGINAL REF. NO.
23. PRIOR AUTHORIZATION NUMBER

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. #
1	MM	DD	YY	MM	DD	YY	11		J7321		A		1		NPI	
2	MM	DD	YY	MM	DD	YY	11		2061*	**	A		1		NPI	
3	MM	DD	YY	MM	DD	YY	11		992**	**	A		1		NPI	
4															NPI	
5															NPI	

Box 24D: Product/Procedure Code
- Enter the appropriate HCPCS code, e.g.: J7321 for SUPARTZ FX
- Enter the appropriate CPT code(s) and modifier(s), e.g.:
  - Administration: 2061* (attach modifier 50 for bilateral injections and modifier LT or RT for unilateral injections)
  - Visit: 992** (attach modifier 25 for a level 1 to 5 physician visit that is separately identifiable from the drug administration service; attach modifier 57 for a decision for surgery on the same day)
  - Asterisks indicate additional digits are required. Final code depends on medical record documentation
  - Some payers may require modifier EJ, usually following the first injection, to indicate subsequent injections in a series of injections. Do not use this modifier for the first injection of each series of injections. Injection of the left knee is a separate series from injection of the right knee

For all subsequent injections, submit the appropriate codes based on the services documented in the medical record.

Always include valid codes on claims to payers. Contact your provider-relations representative or payer website to confirm the requirements.

Claims Filing Checklist

A clean claim is defined as a claim free of errors. In order to ensure prompt and accurate payment, it is important to ensure that the information on the claim is accurate and error free. Consider the following:

- ☑ Always verify the patient's insurance eligibility and coverage before injecting
- ☑ Double check claims for simple/clerical errors
- ☑ Check for codes that are billed but not supported by documentation, have incorrect dates of services, or have missing provider or patient data
- ☑ Verify the codes entered on the claim form; a simple transposition error can delay processing or cause the claim to be processed incorrectly
- ☑ Check payer policies for covered diagnoses and treatment frequency limits
  - Ensure each service is linked to the appropriate diagnosis code and the frequency (e.g., units) is within appropriate limits
- ☑ Most electronic claims processing software and/or clearinghouses have the capability to perform simple proofreading functions
  - This allows for corrections to be made before the claim is submitted to the third-party payer

Common Denial Reasons[8,9]

Understanding the reason for a denial will determine next steps for resolving the denial. Here are some common reasons a claim may be denied and actions one may take to overturn the denial.

Error: Clerical (Technical)

- Incorrect patient ID, missing signatures
- Missing or incorrect code (e.g., transposed numbers)
- Incorrect units

Required Action:

- *Call to correct*
- *Prepare and submit a corrected claim*

Error: Billing

- Non-covered or non-allowed service
- Service was unbundled
- Incorrect placement of service code
- Duplicate claim
- Invalid code

Required Action:

- *Prepare and submit a corrected claim*
- *Prepare and submit an appeal*

Error: Medical Necessity

- The diagnosis code is not covered for the services performed
- Medical record documentation does not support the services performed as medically necessary and in accordance with the respective medical policy in place

Required Action:

- *Prepare and submit an appeal*

Strategies for Appealing Denied Claims

In some cases, a denied claim can be resolved over the phone, but in other cases, an HCP may need to complete and submit an appeal letter in order to overturn a denied claim. Here are some strategies for working through this process:

• What is the limit for timely filing an appeal?

Limits for timely filing vary by level of appeal and by payer. For example, the first level of appeal (reconsideration) for Medicare requires appeal submission within 120 days of receipt of denial notice[10]

TIP: File the claim appeal as soon as possible and within timely filing limits

• What is the method for submission (e.g., electronic, fax, or mail)?

HCPs may submit written requests via mail, fax, or secure internet portal/application

TIP: Verify that faxing or submission through a portal/application is an option to submit an appeal, as the payer has discretion in what format they use

• How long does the appeal process usually take?

Decision times vary by level of appeal and payer

TIP: Timelines for reprocessing the claim can be delayed due to incomplete requests

• How will the payer communicate the appeal decision to the HCP?

Payers generally will respond via the method used in the request, followed by a letter received by mail

TIP: Timelines for actual payment after the decision date can vary by payer. Check with the payer so you know when to follow up if you do not receive payment

• Is there a particular form that must be completed?

Check with the payer to confirm if they have a specific form or guidelines for submitting an appeal

TIP: Payers will often post template forms for download on their website. If you cannot locate the form online, contact the payer for additional guidance

Sample Template Letters for Bioventus HA Products

These sample letters are intended to provide an example of how to structure a letter of appeal and letter of medical necessity. The HCP should modify the format of these letters as appropriate.

SAMPLE LETTER OF APPEAL

LETTER OF APPEAL
[To be completed by prescriber and printed on letterhead]

[Date]

[Name of Claim Reviewer]
[Insurance Company]
[Address]
[City, State, Zip]

Re: [Patient Name]
[Patient Prescription Plan Policy Number and Group Number]
[Patient ID]
[Patient Date of Birth]

Dear **[Claim Reviewer]:**

You have indicated that my request for coverage of **[product name]** for my patient has been denied (see attached copy of denial letter).

I am writing to appeal this decision and appreciate your reconsideration of coverage, as it continues to be my professional determination that **[product name]** is medically necessary for the well-being of this patient.

[Product name] is indicated for 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).

To document the rationale for medical necessity for this patient, I am providing the patient's medical history, **[his or her]** diagnosis, and a copy of the **[product name]** FDA-approved labeling.

[Insert a brief summary of patient's medical history and physician's rationale for prescribing (product name)]

Given the information that I have provided about the patient, I respectfully request the attached denied claim be reconsidered for payment coverage.

Thank you in advance for your immediate attention to this appeal request. Please contact me if you have any questions or need additional documentation to process the claim.

Sincerely,

[Physician's Name]
[Physician's License Number]
[Physician Contact Information]

Attachments:
Denial Letter
[Product Name] FDA Instructions for Use

SAMPLE LETTER OF MEDICAL NECESSITY

LETTER OF MEDICAL NECESSITY
[To be completed by prescriber and printed on letterhead]

[Date]

[Insurer Name]
[Attn:]
[Address]
[City, State, Zip]

Re: **[Patient's Name]**
[Patient's Prescription Plan Policy Number]

Dear **[Insurer]:**

I am writing to request prior authorization for coverage of hyaluronic acid (HA) treatment for my patient, for whom I have prescribed HA in accordance with the following instructions:

Specifics of the prescription: **[insert product name, strength, quantity, directions, refills]**

The FDA approved **[product name]** 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 analgesic therapy (e.g., acetaminophen).

HA products are used for joint lubrication in the treatment of pain associated with knee OA. HA is a naturally occurring molecule that provides lubrication and cushioning in a normal joint. Knee OA involves the breakdown, or degeneration of cartilage and synovial fluid that cushion and lubricate joint tissues within the knee.

It is my professional judgment that **[product name]** is a medically necessary treatment for my patient. This letter provides information about the patient's medical history and diagnosis and my rationale for this course of treatment.

The history and clinical course for my patient are as follows: **[insert information concerning patient's condition, including diagnosis code and clinical course prior to this course of therapy]**.

Please contact me if you require additional information. You can reach me at **[insert telephone number and email address].**

Sincerely,

[Prescriber Name]
[Prescriber License Number]
[Prescriber Contact Information]

Attachments:
[Product Name] FDA Instructions for Use

References

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Notes