

Reimbursement Guide

for SynoJoynt® 1% Sodium Hyaluronate

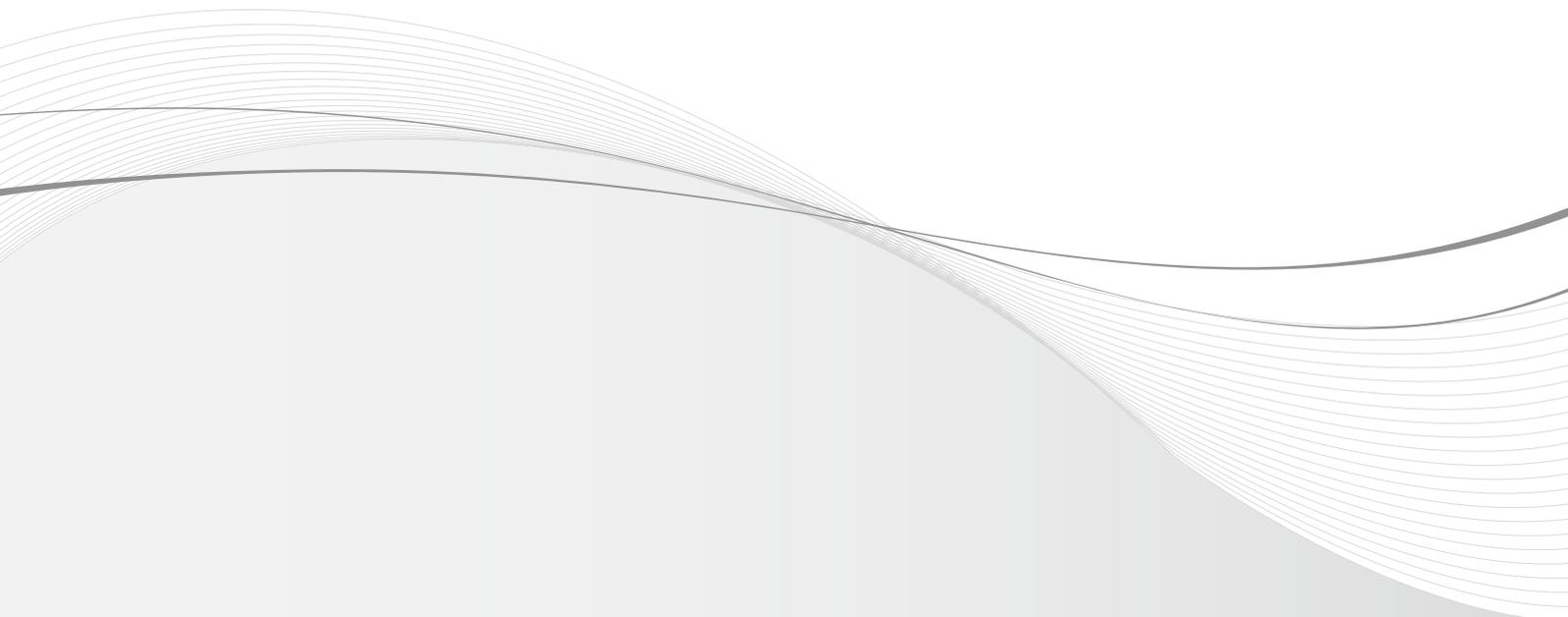


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Description and Indication

SynoJoynt® sodium hyaluronate solution is a sterile, nonpyrogenic, clear, viscoelastic solution of hyaluronan contained in a single-use, prefilled syringe. It is a viscous solution of sodium hyaluronate in buffered physiological sodium chloride. Sodium hyaluronate is a high-molecular-weight fraction (approximately $2.5 \text{ da} \times 10^6 \text{ da}$) of a natural, complex sugar polymer consisting of the repeating disaccharide units Na-glucuronate and N-acetylglucosamine.

SynoJoynt sodium hyaluronate is indicated for the treatment of pain from osteoarthritis (OA) of the knee in patients who have failed to respond adequately to conservative, nonpharmacologic therapy or simple analgesics (eg, acetaminophen).

Please see full prescribing information at ArthrexRSP.com.

Dosage and Administration

Each prefilled syringe of SynoJoynt solution contains 20 mg sodium hyaluronate, 17 mg sodium chloride, 0.8 mg disodium hydrogen phosphate heptahydrate, 0.06 mg sodium dihydrogen phosphate, monohydrate, and QS to 2 mL of water for injection. SynoJoynt sodium hyaluronate is intended to be injected into the knee joint and is administered as a regimen of 3 intra-articular injections given 1 week apart, for a total of 3 injections.

Using This Reimbursement Guide

This guide is provided solely for information purposes and is designed to provide health care professionals with general coding and claims information related to SynoJoynt sodium hyaluronate. There are many factors that affect how payors will cover and pay for SynoJoynt sodium hyaluronate, including the site of service where it is administered, what type of health insurance the patient has, and the type of benefits the payor offers. This guide contains the following information:

- Coding for SynoJoynt sodium hyaluronate by site of service, including coding for the diagnosis and administration procedure
- Contact information for the Arthrex Reimbursement Support Program (RSP)
- Prior authorization checklist
- Sample claim forms that illustrate the key components that may be required by a payor when completing a claim for SynoJoynt sodium hyaluronate
- Tips for submitting clean claims and strategies for appealing denied claims

Arthrex RSP is available to support health care providers with coding, coverage, and reimbursement questions to help facilitate appropriate patient access to Arthrex biologic products.

Need assistance?

Visit ArthrexRSP.com or call the Arthrex RSP hotline at (844) 604-6359 between 9:00 AM and 6:00 PM ET, Monday through Friday.

Overview of Arthrex Reimbursement Support Program

Coverage and coding for SynoJoynt® 1% sodium hyaluronate solution may vary depending on the patient's type of health insurance and the site of service where the product is administered (ie, physician office, hospital outpatient department, or ambulatory surgical center). It will be important to conduct a benefit investigation for each patient in order to verify the following:

- Coverage and utilization restrictions, such as prior authorization, for SynoJoynt sodium hyaluronate
- Patient copayment or coinsurance for SynoJoynt sodium hyaluronate and administration services
- Appropriate coding for SynoJoynt sodium hyaluronate
- Provider's network status with plan
- Upon request, Arthrex RSP will provide prior authorization support by submitting, if possible, any of the information available for a verbal prior authorization if the payer will accept it from the Arthrex RSP hotline

In some circumstances, upon request, Arthrex RSP may provide prior authorization support by furnishing information available for a verbal prior authorization. Arthrex RSP offers reimbursement information to practices, ambulatory surgical centers, and hospital providers. Reimbursement counselors are available to support health care professionals with the following:



Benefit verification for medical benefits



Prior authorization support



Claims management information



Appropriate coding and billing support



Appeals information

Disclaimer

Information described in the SynoJoynt sodium hyaluronate reimbursement guide is intended solely for use as a resource tool to assist physician office and ambulatory surgical center billing staff regarding potential reimbursement challenges. It is the sole responsibility of the treating health care professional to diagnose and treat the patient, and to confirm coverage, coding, and claim submission guidance with the patient's health insurance plan to ensure claims are accurate, complete, and supported documentation in the patient's medical record. Any determination regarding if and how to seek reimbursement should be made only by the appropriate members of the staff, in consultation with the physician, and in consideration of the procedure performed or therapy provided to a specific patient. Arthrex Inc. 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 SynoJoynt sodium hyaluronate reimbursement guide is current as of November 2023.

The content provided in the SynoJoynt sodium hyaluronate reimbursement guide is for informational purposes only. The Arthrex Reimbursement Support Program does not guarantee reimbursement by third-party payors. For details on the specific services provided by the Arthrex Reimbursement Support Program, please see the following section of the SynoJoynt sodium hyaluronate reimbursement guide. Reimbursement specialists at the Arthrex Reimbursement Support Program are available to assist you with questions related to

reimbursement support and access services for therapy with SynoJoynt sodium hyaluronate at (844) 604-6359, from 9:00 AM to 6:00 PM ET, Monday through Friday.

The information provided in this handout was obtained from many sources and is subject to change without notice as a result of changes in reimbursement laws, regulations, rules, and policies. All content is informational only, general in nature, and does not cover all situations or all payors' rules and policies. This content is not intended to instruct medical providers on how to use or bill for health care procedures, including new technologies outside of Medicare national guidelines. A determination of medical necessity is a prerequisite that we assume will have been made prior to assigning codes or requesting payments. Medical providers should consult with appropriate payors, including Medicare fiscal intermediaries and carriers, for specific information on proper coding, billing, and payment levels for health care procedures. It is the sole responsibility of the medical provider to determine the appropriate coding.

This handout's information represents no promise or guarantee concerning coverage, coding, billing, and payment levels. Arthrex specifically disclaims liability or responsibility for the results or consequences of any actions taken in reliance on information in this handout or through the Arthrex Reimbursement Support Program. The SynoJoynt sodium hyaluronate reimbursement guide does not constitute legal, coding, coverage, reimbursement, business, clinical, or other advice and no warranty regarding completeness or accuracy is implied.

Arthrex RSP assists health care professionals by providing information that helps them appropriately expedite patient access to care. With the submission of complete information to the program, many reimbursement research requests can be finished in 1 to 2 business days.

It is helpful to have the following information available when contacting an Arthrex RSP reimbursement counselor:



Physician's name, address, phone number, and provider number (NPI, TID, etc)



Patient's name, date of birth, address, and Social Security number



Insurance company name, phone number, and fax number



Policy holder name



Policy identification and group numbers



Diagnosis



Site of care



Office contact name and phone number

In addition to reimbursement assistance, Arthrex RSP can provide additional resources that may include the following:

- Patient case management information
- Product ordering management

In order to use Arthrex RSP, health care professionals are asked to fill out and sign a benefit verification request form. You can obtain the form by contacting Arthrex RSP, accessing it at [ArthrexRSP.com](https://arthrexrsp.com), or requesting one from your Arthrex sales representative.

Need assistance?

Visit [ArthrexRSP.com](https://arthrexrsp.com) or call the Arthrex RSP hotline (844) 604-6359 between 9:00 AM and 6:00 PM ET, Monday through Friday.

Coding and Associated Services for SynoJoynt® 1% Sodium Hyaluronate Solution

Many payors recognize Healthcare Common Procedure Coding System (HCPCS) Level II national codes to report products (drugs and medical devices), supplies, and services not included in the Current Procedural Terminology (CPT®) codes.

Payors may accept the following HCPCS code for SynoJoynt sodium hyaluronate:

HCPCS Code	Description	Billing Units	Site of Service	Claim Form (Location)	Payor Type
J7331	Hyaluronan or derivative, SynoJoynt, for intra-articular injection, 1 mg	20 (1 mg = 1 billing unit; each syringe = 20 billing units)	Physician office	CMS-1500 (Box 24D)	All
			Hospital outpatient	CMS-1450 (Field 44)	
			Ambulatory surgical center	CMS-1450 (Field 44)	

SynoJoynt sodium hyaluronate is supplied in a 3 mL single-use syringe containing 2 mL of product

- Each milliliter contains 10 mg sodium hyaluronate
- 2 mL contains 20 mg sodium hyaluronate
- Administration of SynoJoynt sodium hyaluronate does not vary by patient

Product Identifiers

For devices such as SynoJoynt sodium hyaluronate, the manufacturer may have a unique Product Code and/or Unique Device Identification (UDI) number. Proper billing—especially to Medicare, Medicaid, or via electronic interchange—may require the Product Code or UDI be submitted on the claim form. For example:

Product Code for SynoJoynt Sodium Hyaluronate	Unique Device Identifier
82197-0721-16	00888867413689

Medicare reimburses SynoJoynt sodium hyaluronate at ASP+6%.

Source: Medicare Claims Processing Manual Chapter 17 (Rev. 10329, 08-28-20) Transmittal 20.1.3 <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c17.pdf>. Contact private payors or consult contracts for their reimbursement amounts.

Coding for Administration Services

CPT codes may be used to identify professional services (eg, administration procedure) provided in the physician office.

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

Modifier	Modifier Description
RT	Right side (used to identify procedures performed on the right side of the body)
LT	Left side (used to identify procedures performed on the left side of the body)
50	Bilateral procedure
EJ	Indicates subsequent injections of a series. Do not use for first injection of each series.
JW	Discarded drug not administered (drug amount discarded/not administered to any patient)
JZ	Zero drug wasted (zero drug amount discarded/not administered to any patient)

CPT (Current Procedural Terminology) is a registered trademark of the American Medical Association.

ICD-10-CM Diagnosis Codes

International Classification of Diseases, 10th Revision, Clinical Modification (ICD-10-CM) diagnosis codes are used to report diseases and conditions. ICD-10-CM diagnosis codes identify why a patient needs treatment by documenting the medical necessity for prescribing SynoJoynt® sodium hyaluronate. Coding to the highest level of specificity may expedite the claims adjudication process. The following ICD-10-CM diagnosis codes are consistent with the product indications. Arthrex RSP does not offer product support for off-label indications. The following diagnosis codes may be appropriate to describe patients with osteoarthritis of the knee; however, you—as the patient’s health care provider—are ultimately responsible for independently determining what code(s) are appropriate based on your clinical assessment of the patient:

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

Coding for SynoJoynt sodium hyaluronate may vary by payor type and plan type (ie, Medicare, private payor, Medicaid). Upon request, Arthrex RSP may conduct appropriate benefit verifications that provide coverage and coding information that is specific to your patient’s health insurance coverage. All information and submissions to CoPilot must be truthful, accurate, nondeceptive, and/or of known application to the particular patient. The program is available Monday through Friday from 9:00 AM to 6:00 PM ET at (844) 604-6359.

Medicare National Average Reimbursement Rate Information

Site of Service	CPT Code	Website for Look-up
Physician Office	20610	https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PFSlookup/index.html
	20611	
Hospital Outpatient	20610	https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Addendum-A-and-Addendum-B-Updates.html
	20611	
Ambulatory Surgical Center	20610	https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ASCPayment/11_Addenda_Updates.html
	20611	

Reimbursement rates for CPT codes vary by geography; consult the CMS website for regional rates applicable to the practice or contact the local Medicare administrative contractor for regional rates.

Prior Authorization Checklist

Arthrex RSP may assist you with obtaining information for prior authorization (PA) for SynoJoynt® 1% sodium hyaluronate solution. Alternatively, the checklist below may be used to ensure that you are obtaining the necessary information from your patient's insurer.

Patient Name:	DOB:
Payor Name:	Phone:
	Date:

Questions to Ask	Answers		
Is a PA required?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	
What information is needed by the insurer for the PA?	<input type="checkbox"/> Diagnosis	<input type="checkbox"/> Previous therapy	<input type="checkbox"/> Chart notes
	<input type="checkbox"/> Other:		
Does the patient need to have a failure, contraindication, or intolerance to the following treatment options?	<input type="checkbox"/> Nonpharmacologic (eg, exercise, physical therapy, weight loss if overweight) <input type="checkbox"/> Intra-articular corticosteroids <input type="checkbox"/> Nonsteroidal anti-inflammatory medications (eg, ibuprofen) <input type="checkbox"/> Non-narcotic analgesics (eg, acetaminophen)		
Does the patient need to have documented symptomatic OA of the knee?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	
Does the patient need to have tried any other medications for the condition?	<input type="checkbox"/> Yes (if yes, complete below) Medication/therapy:	<input type="checkbox"/> No	Duration of therapy:
Does the insurer have a specific PA form?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	
If the insurer has a specific PA form, how is the form obtained? Provide website, provider portal address, and/or fax number.	Online:	Insurer provider portal:	Fax:
How is the PA submitted to the insurer? Provide phone, fax, and/or portal address.	Phone:	Insurer provider portal:	Fax:
Will the insurer provide a PA number to include on the claim form?	<input type="checkbox"/> Yes (if yes, complete below) PA number:	<input type="checkbox"/> No	
How long does it take the insurer to review the PA request?			
How long is the PA valid for SynoJoynt sodium hyaluronate?			

Need assistance?

Visit ArthrexRSP.com or call the Arthrex RSP hotline (844) 604-6359 between 9:00 AM and 6:00PM ET, Monday through Friday.

Sample CMS-1450 (UB-04) Claim Form for SynoJoynt® 1% Sodium Hyaluronate Solution

1		2		3a PAT. CNTL. #		4 TYPE OF BILL	
				b. MED. REC. #			
				5 FED. TAX NO.		6 STATEMENT COVERS PERIOD FROM	
						7 THROUGH	
8 PATIENT NAME a			9 PATIENT ADDRESS a				
b			c			d	
10 BIRTHDATE	11 SEX	12 DATE	ADMISSION 13 HR 14 TYPE 15 SRC	16 DHR	17 STAT	CONDITION CODES 18 19 20 21 22 23 24 25 26 27 28	
31 OCCURRENCE CODE		DATE		32		37	
38		39 VALUE CODES CODE		40 VALUE CODES AMOUNT		41 VALUE CODES CODE	
		a		b		c	
		b		c		d	
		c		d		e	
		d		e		f	
42 REV. CD.	43 DESCRIPTION	44 HCPCS / RATE / HIPPS CODE		45 SERV. DATE	46 SERV. UNITS	47 TOTAL CHARGES	48 NON-COVERED CHARGES
1 0636	Drugs requiring detailed information (SYNOJOYNT)	J7331		MM DD YY	20	XXX : XX	
2							
3 0510	Clinic visit (knee joint injection in clinic)	20610-LT		MM DD YY	1	XXX : XX	
4							
5							
6							
7							
PAGE ____ OF ____		CREATION DATE		TOTALS			
50 PAYER NAME		51 HEALTH PLAN ID		52 REL. INFO	53 ASG. BEN.	54 PRIOR PAYMENTS	55 EST. AMOUNT DUE
A		B		C		D	
B		C		D		E	
C		D		E		F	
58 INSURED'S NAME		59 P. REL.		60 INSURED'S UNIQUE ID		61 GROUP NAME	
A		B		C		D	
B		C		D		E	
C		D		E		F	
64 DOCUMENT		65		66		67	
M17.12							
69 ADMIT DX		70 PATIENT REASON DX		71 ICD-10 CODE		72 ECI	
74 PRINCIPAL PROCEDURE CODE		a. OTHER PROCEDURE CODE		b. OTHER PROCEDURE CODE		75	
MM DD YY							
c. OTHER PROCEDURE CODE		d. OTHER PROCEDURE CODE		e. OTHER PROCEDURE CODE		76 ATTENDING NPI	
						LAST FIRST	
						77 OPERATING NPI	
						LAST FIRST	
80 REMARKS		81CC a		b		78 OTHER NPI	
		c		d		LAST FIRST	
						79 OTHER NPI	
						LAST FIRST	

This document is provided for guidance only. Please call the Arthrex RSP hotline at (844) 604-6359.

Fields 42-43:
Enter the appropriate revenue code and description corresponding to the HCPCS code in Field 44
- **0636** for SynoJoynt sodium hyaluronate
- **0510** for knee joint injection administered in the outpatient clinic
Note: Other revenue codes may apply

Field 44: Enter appropriate CPT/HCPCS codes and modifiers
- **Drug: J7331 hyaluronan or derivative, SynoJoynt sodium hyaluronate, for intra-articular injection, 1 mg**
- Administration: **20610** for knee joint injection without ultrasound guidance
- Modifier **LT** (left knee) or **RT** (right knee)

Field 46: Enter the appropriate number of units of service
- Enter 20 units of **J7331** to denote use of SynoJoynt sodium hyaluronate for 1 syringe

Field 66: Identify the type of ICD diagnosis code used

Fields 67 and 67A-67Q: Enter the appropriate diagnosis code ICD-10-CM; **M17.12** for unilateral primary osteoarthritis of the left knee (specific 4th and 5th digits depend on medical record documentation)
Note: Other diagnosis codes may apply

Reasons for denied claims may include:

- Use of incorrect codes on claim
- Missing or incorrect information on claim form (eg, misspelled patient name)
- Provider's network status with plan
- Incorrect number of units reported
- Omission of letter of medical necessity
- Failure to obtain a PA before initiating treatment or failure to include the PA approval number on the claim form
- Since payors may have different guidelines for coding and claims filing, consider checking with individual plans to research claims submission requirements

It is possible that not all payors will be familiar with SynoJoynt® 1% sodium hyaluronate solution because it is a newer product and billed with its own unique HCPCS code. Payors may need more information about a product if they are unfamiliar with it, and may request additional information about the patient's treatment or diagnosis in order to determine whether a treatment is medically necessary.

A letter of medical necessity may help to explain why SynoJoynt sodium hyaluronate is medically necessary for the patient's treatment. Claims may include supporting materials such as:

- Customized letter of medical necessity
- Invoice
- FDA approval letter
- Chart notes
- Patient medical history
- Prior therapies
- Package insert

Important Safety Information

Indications

SynoJoynt® 1% sodium hyaluronate is indicated for the treatment of pain in osteoarthritis (OA) of the knee in patients who have failed to respond adequately to conservative nonpharmacologic therapy and simple analgesics (eg, acetaminophen).

Contraindications

Do not use to treat patients who have a known hypersensitivity to hyaluronan preparations. Do not use to treat patients with knee joint infections or to treat patients with infections or skin disease in the area of the injection site.

Warnings

Do not concomitantly use disinfectants containing quaternary ammonium salts or chlorhexidine for skin preparations because hyaluronan can precipitate in their presence. Do not inject intravascularly because intravascular injections of SynoJoynt 1% sodium hyaluronate may cause systemic adverse events.



This description of technique is provided as an educational tool and clinical aid to assist properly licensed medical professionals in the usage of specific Arthrex products. As part of this professional usage, the medical professional must use their professional judgment in making any final determinations in product usage and technique. In doing so, the medical professional should rely on their own training and experience, and should conduct a thorough review of pertinent medical literature and the product's directions for use. Postoperative management is patient-specific and dependent on the treating professional's assessment. Individual results will vary and not all patients will experience the same postoperative activity level and/or outcomes.



Arthrex manufacturer,
authorized representative,
and importer information
(Arthrex eIFUs)



US patent information

arthrex.com