



HYALGAN[®]
(sodium hyaluronate)

REIMBURSEMENT GUIDE

IMPORTANT SAFETY INFORMATION

Important Safety Information

- HYALGAN® 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 to simple analgesics (eg, acetaminophen)
- HYALGAN® 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. Transient increases in inflammation in the injected knee following HYALGAN® injection have been reported in some patients with inflammatory arthritis. Physicians should evaluate whether HYALGAN® treatment should be initiated when objective signs of inflammation are present. Patients should be advised to avoid any strenuous or prolonged weight-bearing activities within 48 hours following IA injection. Use caution when injecting HYALGAN® into patients who are allergic to avian proteins, feathers, and egg products. Joint effusion, if present, should be removed prior to injection
- The effectiveness of a single treatment cycle of less than 3 injections has not been established
- In the US clinical trial of 495 patients, the only adverse event showing statistical significance vs placebo was injection-site pain. Other adverse events included gastrointestinal complaints, headache, local ecchymosis and rash, local joint pain and swelling, and local pruritus. However, the incidence of these events was similar in the HYALGAN®-treated and placebo groups. In other clinical studies, the frequency and severity of adverse events occurring during repeat treatment cycles did not increase over that reported for a single treatment cycle
- Rx Only

Please see full Prescribing Information at www.HYALGAN.com.



**HYALGAN®
SUPPORT HOTLINE
1-866-7HYALGAN (1-866-749-2542)**

The HYALGAN® Support Hotline 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 hotline.

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INTRODUCTION

Description and Indication

HYALGAN® is a viscous solution consisting of a high-molecular-weight (500,000 to 730,000 daltons) fraction of purified natural sodium hyaluronate (Hyalectin®) in buffered physiological sodium chloride, with a pH of 6.8 to 7.5. Sodium hyaluronate is extracted from rooster combs. Hyaluronic acid is a natural complex sugar of the glycosaminoglycan family and is a long-chain polymer containing repeating disaccharide units of Na-glucuronate-N-acetylglucosamine.

HYALGAN® 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 to simple analgesics (eg, acetaminophen).

Please see full Prescribing Information at www.HYALGAN.com.

Dosage and Administration

HYALGAN® is administered by intra-articular injection. A treatment cycle consists of 5 injections given as 1 injection per week for 5 weeks. Some patients may experience benefits with 3 injections given as 1 injection per week for 3 weeks. This has been noted in studies reported in the literature in which patients treated with 3 injections were followed for 60 days.

Using the HYALGAN® Reimbursement Guide

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

Disclaimer

Information described in the HYALGAN® 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. FIDIA FARMACEUTICI S.P.A./FIDIA PHARMA USA INC. do not recommend or endorse the use of any particular diagnosis or procedure code(s) and make 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 HYALGAN® Reimbursement Guide is current as of March 2021.

Information provided in the HYALGAN® Reimbursement Guide is for your guidance only. The *HYALGAN® Support Hotline* 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 *HYALGAN® Support Hotline*, please see the final section of the HYALGAN® Reimbursement Guide.

Reimbursement specialists at the *HYALGAN® Support Hotline* are available to assist you with questions related to reimbursement support and access services for therapy with HYALGAN®. To contact a reimbursement specialist, please call **1-866-7-HYALGAN (1-866-749-2542)**, Monday to Friday, from 9:00 AM to 8:00 PM EST.

BASICS OF REIMBURSEMENT

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



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.

Below, major coding systems and their relevant sites of services are outlined.*

Coding System	Description	Site of Service
Healthcare Common Procedure Coding System (HCPCS) Level II Codes	Alpha-numeric coding system used to report specific drugs, supplies, and other healthcare equipment used during the course of medical therapy	Physician office Hospital outpatient
International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) Diagnosis Codes [†]	Numeric codes used to report patient conditions, illnesses, or symptoms, which support medical necessity for need of healthcare services	Physician office Hospital outpatient
Current Procedural Terminology (CPT) Codes (HCPCS Level I Codes)	Numeric coding system used to report medical services and procedures related to the administration of a drug/product as provided by healthcare professionals	Physician office Hospital outpatient
Revenue Codes	Numeric codes used by hospitals to report on services and supplies to specific cost centers	Hospital outpatient

*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 HYALGAN® and its administration are outlined here.

[†]As of October 1, 2015 ICD-10-CM codes will be required on claims.

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 products are used for a medically reasonable and necessary indication. Typically, coverage is provided under 2 benefit structures: the medical benefit and/or the pharmacy benefit. Both public (Medicare/ Medicaid) and private payers use medical and pharmacy benefit structures.




REIMBURSEMENT

Reimbursement is the amount a payer renders to a healthcare provider plus patient out of pocket, deductibles and/or copays for covered therapies and services. Typically, the payment methodology and payment amount vary based on the site of service where the care is provided.

HYALGAN® 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, which provides coverage to 49 million beneficiaries, and is administered through the following 4 benefit categories:

	Part A Hospital Insurance	Covers inpatient hospital, skilled nursing facility, hospice, and certain home healthcare services. Reimbursement is a prospective payment with a single payment inclusive of all service, supplies, and drugs.
	Part B Medical Insurance	Covers outpatient services, physician services and physician-administered drugs in the 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 self-administered drugs through Part C or standalone Prescription Drug Plans administered by private organizations.

Medicare is expected to reimburse healthcare providers for HYALGAN® when provided to a patient as a medically necessary therapy in the physician office or hospital outpatient settings of care. Because HYALGAN® is a physician-administered product, it is covered under Medicare Part B.

COVERAGE: Medicare (*continued*)

For products that are covered under Medicare Part B, coverage decisions are typically made through a National Coverage Determination (NCD) or Local Coverage Determinations (LCDs). Centers for Medicare and Medicaid Services (CMS) issue NCDs and Medicare Administrative Contractors (MACs) issue LCDs. LCDs are specific to a MAC's jurisdiction and each state, meaning that specific coverage criteria for a product and its administration, as well as coding requirements, may vary by Medicare contractor. NCDs are rare for drugs and other similar products.

Please consult your MAC to determine if any LCDs apply to HYALGAN®. To verify a patient's Medicare coverage information, please call the *HYALGAN® Support Hotline* at **1-866-7-HYALGAN (1-866-749-2542)**, Monday to Friday, from 9:00 AM to 8:00 PM EST.

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 HYALGAN® when used for its FDA-approved indication. Private payers may implement restrictions, such as requiring prior authorization and/or other utilization controls. Reimbursement may also vary significantly by the specific contracts that are negotiated between providers and private payers.

Requesting plan-specific coverage information on HYALGAN® is an important step in understanding your patients' health benefits, especially since private payer plans vary considerably. To verify a patient's private payer plan coverage and reimbursement information, please call the *HYALGAN® Support Hotline* at **1-866-7-HYALGAN (1-866-749-2542)**, Monday to Friday, from 9:00 AM to 8:00 PM EST.

COVERAGE: Medicaid

Most states have direct administration of the program and also contract with managed care organizations to administer the program. Medicaid programs and their MCOs may follow Medicare's coverage policies, while others may create their own coverage guidelines. Typically, Medicaid will cover HYALGAN® when used for its FDA-approved indication. Some programs may implement restrictions, such as requiring prior authorization and/or other utilization controls.

Requesting state or plan-specific coverage information on HYALGAN® is an important step in understanding your patients' benefits, especially since Medicaid programs vary considerably. To verify a patient's Medicaid coverage and reimbursement information, please call the *HYALGAN® Support Hotline* at **1-866-7-HYALGAN (1-866-749-2542)**, Monday to Friday, from 9:00 AM to 8:00 PM EST.

HYALGAN® REIMBURSEMENT IN THE PHYSICIAN OFFICE SETTING

CODING

The codes relevant to HYALGAN® 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 HYALGAN® therapy on page 11.

Note: While the general codes relevant to HYALGAN® 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 HYALGAN® Support Hotline* at **1-866-7-HYALGAN (1-866-749-2542)**, Monday to Friday, from 9:00 AM to 8:00 PM EST for assistance to verify specific or unique payer coding requirements.

On a CMS-1500 claim form, applicable ICD-10-CM diagnosis codes must be reported in Box 21.

ICD-10	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

HCPCS

To report HYALGAN® administration in the physician office, use of the HYALGAN® permanent HCPCS code is appropriate, as noted below:

HCPCS Code	Description
J7321	Hyaluronan or derivative, HYALGAN®, for intra-articular injection, per dose Catalog Number (Also known as the NHRIC) 89122-0724-20

On a CMS-1500 claim form, Box 24D should be used for reporting the HYALGAN® permanent HCPCS code.

Medicaid and some payers require the Catalog Number (NHRIC) on the CMS-1500 claim form, in the shaded area 24A. Some payers require the Catalog Number (NHRIC) code to be preceded by “N4” to indicate and Catalog Number (NHRIC) is following.

CPT

To report the physician administration of HYALGAN®, the following CPT code may be appropriate when HYALGAN® 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	Arthrocentesis, aspiration and/or injection, major joint or bursa (eg, shoulder, hip, knee, subacromial bursa); with ultrasound guidance, with permanent recording and reporting

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 the knee in which HYALGAN® was administered. For bilateral administration of HYALGAN®, some payers may require modifier “-50” (bilateral procedure) to be documented after CPT code 20610. In addition, payers may require EJ modifier, **usually following the first injection**, to indicate subsequent injections in a series of injections to be documented after J-Code. A series of injections for each joint and each treatment, left knee is a separate series from the right knee.

HYALGAN® CMS-1500 SAMPLE CLAIM FORM

1500
HEALTH INSURANCE CLAIM FORM
 APPROVED BY NATIONAL UNIFORM CLAIM COMMITTEE 08/05

PICA PICA

1. MEDICARE MEDICAID TRICARE CHAMPVA GROUP HEALTH PLAN FECA OTHER
 (Medicare #) (Medicaid #) (Sponsor's SSN) (Member ID#) (SSN or ID) (SSN) (ID)

2. PATIENT'S NAME (Last Name, First Name, Middle Initial)
 Doe, John

3. PATIENT'S BIRTH DATE
 MM DD YY 01 01 45 SEX M F

4. INSURED'S I.D. NUMBER (For Program in Item 1)
 123-45-6789A

4. INSURED'S NAME (Last Name, First Name, Middle Initial)
 Doe, John

5. PATIENT'S ADDRESS (No., Street)
 12345 Green Street

6. PATIENT RELATIONSHIP TO INSURED
 Self Spouse Child Other

7. INSURED'S ADDRESS (No., Street)
 12345 Green Street

CITY STATE
 City Town XX

8. PATIENT STATUS
 Single Married Other

9. OTHER INSURED'S NAME (Last Name, First Name, Middle Initial)

10. IS PATIENT'S CONDITION RELATED TO:
 a. EMPLOYMENT? (Current or Previous) YES NO
 b. AUTO ACCIDENT? YES NO PLACE (State) _____
 c. OTHER ACCIDENT? YES NO
 10d. RESERVED FOR LOCAL USE

11. INSURED'S POLICY GROUP OR FECA NUMBER

12. PATIENT'S OR AUTHORIZED PERSON'S SIGNATURE I authorize the release of any medical or other information necessary to process this claim. I also request payment of government benefits either to myself or to the party who accepts assignment below.
 SIGNED _____ DATE _____

13. INSURED'S OR AUTHORIZED PERSON'S SIGNATURE I authorize payment of medical benefits to the undersigned physician or supplier for services described below.
 SIGNED _____ DATE _____

14. ICD-10-CM diagnosis
 14a. ICD-10-CM diagnosis
 14b. NPI

15. IF PATIENT HAS HAD SAME OR SIMILAR ILLNESS, GIVE FIRST DATE MM DD YY
 15a. DATE
 15b. NPI

16. DATES PATIENT UNABLE TO WORK IN CURRENT OCCUPATION
 FROM MM DD YY TO MM DD YY

17. HOSPITALIZATION DATES RELATED TO CURRENT SERVICES
 FROM MM DD YY TO MM DD YY

18. OUTSIDE LAB? YES NO \$ CHARGES _____

19. MEDICAID RESUBMISSION CODE ORIGINAL REF. NO.

20. PRIOR AUTHORIZATION NUMBER

21. DIAGNOSIS OR NATURE OF ILLNESS OR INJURY (Relate Items 1, 2, 3 or 4 to Item 24E by Line)
 1. M17.0

22. HCPCS Code
 Enter HCPCS code for HYALGAN® J7321—Hyaluronan or derivative, HYALGAN®, for intra-articular injection, per dose
 J7321

23. CPT Code
 Enter appropriate CPT code and modifier
 Example: 20610—Arthrocentesis, aspiration, and/or injection; major joint or bursa [eg, shoulder, hip, knee joint, subacromial bursa]
 20610 50

24. A. DATE(S) OF SERVICE From MM DD YY To MM DD YY B. PLACE OF SERVICE C. EMG D. HCPCS E. MODIFIER F. PORTER G. CHARGES H. DAYS OF UNITS I. EPIC/First Pay J. ID. QUAL K. RENDERING PROVIDER ID. #

25. FEDERAL TAX I.D. NUMBER SSN EIN

26. PATIENT'S ACCOUNT NO.

27. ACCEPT ASSIGNMENT? YES NO

28. TOTAL CHARGE \$

29. AMOUNT PAID \$

30. BALANCE DUE \$

31. SIGNATURE OF PHYSICIAN OR SUPPLIER INCLUDING DEGREES OR CREDENTIALS (I certify that the statements on the reverse apply to this bill and are made a part thereof.)

32. SERVICE FACILITY LOCATION INFORMATION

33. BILLING PROVIDER INFO & PH # ()

SIGNED _____ DATE _____

NUCC Instruction Manual available at: www.nucc.org APPROVED OMB-0938-0999 FORM CMS-1500 (08/05)

Box 21: Diagnosis Code
 Enter appropriate ICD-10-CM diagnosis
 Example:
 M17.0—Bilateral primary osteoarthritis of knee

Box 24D: HCPCS Code
 Enter HCPCS code for HYALGAN® J7321—Hyaluronan or derivative, HYALGAN®, for intra-articular injection, per dose

Box 24D: CPT Code
 Enter appropriate CPT code and modifier
 Example:
 20610—Arthrocentesis, aspiration, and/or injection; major joint or bursa [eg, shoulder, hip, knee joint, subacromial bursa]

Box 24G: Days or Units
 Enter number of HYALGAN® units administered
 Example:
 1 service unit for each dose

DISCLAIMER: This HYALGAN® CMS-1500 Sample Claim Form is intended solely for use as a resource tool to assist physician office and hospital outpatient billing staff regarding reimbursement issues. Any determination about 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. FIDIA FARMACEUTICI S.p.A/FIDIA PHARMA USA INC. do 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/legislation are subject to continual change; information contained in this version of the HYALGAN® Reimbursement Guide is current as of March 2021.

REIMBURSEMENT

The following section describes public (Medicare/Medicaid) and private payer reimbursement information relevant to HYALGAN® and its administration in the physician office setting.

Note: Because of variability in coverage and reimbursement across Medicaid and private payer plans, it is particularly important to conduct patient-specific insurance verifications for HYALGAN® therapy for patients with these types of healthcare insurance. To contact a reimbursement specialist for conducting patient-specific coverage and reimbursement, please call the *HYALGAN® Support Hotline* at **1-866-7-HYALGAN (1-866-749-2542)**, Monday to Friday, from 9:00 AM to 8:00 PM EST.

Medicare

When HYALGAN® is provided in the physician office setting, both the product and the services associated with its administration may be reimbursed by Medicare. The payment methodology for HYALGAN® is expected to be based on its Average Sales Price (ASP) plus 6%.* Please note that Medicare's drug and product payment rates change on a quarterly basis. In addition, services that are associated with HYALGAN® administration would be reimbursed based on the Medicare Physician Fee Schedule (MPFS).

HCPCS Code	Description
J7321	Hyaluronan or derivative, HYALGAN®, for intra-articular injection, per dose

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

In general, Medicare pays 80% of the allowed amount of the drug/product and service. Medicare beneficiaries are responsible for 20% of the allowed amount of the drug/product and service once a deductible has been met. If a Medicare beneficiary has a source of secondary coverage, that insurance may be used toward this cost-sharing requirement.

*This allowed payment is subject to quarterly changes

Private Payers

Private payers typically negotiate payment rates for HYALGAN[®], when administered in the physician office setting, that may be based on a fee schedule, a percentage of billed or allowable charges, or a percentage of Wholesale Acquisition Cost (WAC) or ASP. For each patient, cost-sharing requirements, such as coinsurance and annual deductible amounts, will vary by individual insurance plan.

Medicaid

State Medicaid programs have different payment rates for HYALGAN[®] when administered in the physician office setting. Medicaid payment for HYALGAN[®] and its associated administration services may be based on state-specific or MCO fee schedules. In the physician office setting, HYALGAN[®] may be reimbursed based on methodologies such as a percentage of WAC or invoice price. Certain state Medicaid programs may require nominal cost-sharing by Medicaid beneficiaries for drugs/products and services.

HYALGAN® REIMBURSEMENT IN THE HOSPITAL OUTPATIENT SETTING

CODING

Codes relevant to HYALGAN® and its administration in the hospital outpatient setting are described in the following section. For more information on reporting various codes in the hospital outpatient site of care, please refer to the sample CMS-1450/UB-04 claim form for HYALGAN® therapy on page 16.

Note: While the general codes relevant to HYALGAN® therapy in the hospital outpatient 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 *HYALGAN® Support Hotline* at **1-866-7-HYALGAN (1-866-749-2542)**, Monday to Friday, from 9:00 AM to 8:00 pm EST for assistance to verify specific or unique payer coding requirements.

On a CMS-1450/UB-04 claim form, applicable ICD-10-CM diagnosis codes must be reported in Box 66.

ICD-10	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

HCPCS

To report HYALGAN® administration in the hospital outpatient setting, use of the HYALGAN® permanent HCPCS code is appropriate, as noted below:

HCPCS Code	Description
J7321	Hyaluronan or derivative, HYALGAN®, for intra-articular injection, per dose Catalog Number (Also known as the NHRIC) 89122-0724-20

On a CMS-1450/UB-04 claim form, Box 44 and Box 46 should be used for reporting the HYALGAN® permanent HCPCS code and the number of units administered, respectively.

CPT

To report the physician administration of HYALGAN®, the following CPT code may be appropriate when HYALGAN® is administered in the hospital outpatient setting:

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

CPT codes should be reported in Box 44 of the CMS-1450/UB-04 claim form as well.

MODIFIERS: In certain instances, payers may require modifier “-RT” (right side) or “-LT” (left side) to be documented after CPT code 20610/20611 to specify which knee HYALGAN® was administered to. For bilateral administration of HYALGAN®, some payers may require modifier “-50” (bilateral procedure) to be documented after CPT code 20610/20611.

Use an “EJ” modifier on drug codes to indicate subsequent injections of a series. Do not use this modifier for the first injection of each series of injections. A series is defined as the set of injections for each joint and each treatment. Injection of the left knee is a separate series from injection of the right knee.

Revenue Codes

When prescribing HYALGAN® therapy within the hospital outpatient setting, revenue codes may also be used to report services and supplies that are utilized during treatment.

Revenue Code	Description
0636	Drugs requiring detailed coding
0510	Clinic, general

On the CMS-1450/UB-04 claim form, revenue codes should be documented in Box 42. Revenue code 0636, however, must be listed as the same reporting line as J7321 (HYALGAN®), since it describes detailed coding for drugs/products.

HYALGAN® CMS-1450/UB-04 SAMPLE CLAIM FORM

1		2		3a PAY CNTL # b. MED. REC. #		4 TYPE OF BILL 131	
8 PATIENT NAME Doe, John				9 PATIENT ADDRESS 12345 Green Street, City Town, XX, 10101			
10 BIRTHDATE 01/01/1945		11 SEX M		12 DATE		13 HR	
31 OCCURRENCE DATE		32 OCCURRENCE DATE		33 OCCURRENCE DATE		34 OCCURRENCE DATE	
42 REV. CD. 0636		43 DESCRIPTION Drugs requiring detailed coding		44 HCPCS / ICD-10 / NPPS CODE J7321		45 SERV. DATE MM/DD/YY	
0510		Clinic, general		2060 - 50		MM/DD/YY	
46 SER. UNITS X		47 TOTAL CHARGES XXX XX		48 NON-COVERED CHARGES		49	
X		XXX XX					
PAGE OF				CREATION DATE		TOTALS	
50 PAYER NAME		51 HEALTH PLAN ID		52 FIEL. SFD		53 ANL. RES.	
54 PRIOR PAYMENTS		55 EST. AMOUNT DUE		56 NPI		57 OTHER PRV ID	
58 INSURED'S NAME		59 FIEL. 60 INSURED'S UNIQUE ID		61 GROUP NAME		62 INSURANCE GROUP NO.	
63 EMPLOYER NAME		64		65		66	
M17.0		67		68		69	
3E0U3GC		70		71		72	
73		74		75		76	
77		78		79		80	

Box 44: HCPCS Code
Enter HCPCS code for HYALGAN® J7321—Hyaluronan or derivative, HYALGAN®, for intra-articular injection, per dose

Box 46: Service Units
Enter number of HYALGAN® units administered
Example: 1 service unit for each dose

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

Box 44: CPT Code
Enter appropriate CPT code and modifier
Example: 20610—Arthrocentesis, aspiration, and/or injection; major joint or bursa [eg, shoulder, hip, knee joint, subacromial bursa]

SAMPLE

Field 66: Identify the type of ICD diagnosis code used
- Enter a "0" for ICD-10-CM

Fields 67 and 67A-67Q: Enter appropriate ICD-10-CM diagnosis M17.0-Bilateral primary osteoarthritis of knee (specific 4th and 5th digits depend on medical record documentation)
Note: Other diagnoses codes may apply

Box 74: Principal Procedure Code & Date
Enter principal ICD-10-PCS procedure code and date
Example: 3E0U3GC for percutaneous knee joint injection of a therapeutic substance

DISCLAIMER: This HYALGAN® CMS-1450/UB-04 Sample Claim Form CMS-1450/UB-04 is intended solely for use as a resource tool to assist physician office and hospital outpatient billing staff regarding reimbursement issues. Any determination about 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. FIDIA FARMACEUTICI S.p.A./FIDIA PHARMA USA INC. do 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/legislation are subject to continual change; information contained in this version of the HYALGAN® Reimbursement Guide is current as of March 2021.

PAYMENT

The following section describes public (Medicare/Medicaid) and private payer payment information relevant to HYALGAN® and its administration in the hospital outpatient setting.

Note: Because of variability in payment across Medicaid and private payer plans, it is particularly important to conduct patient-specific insurance benefit verifications for HYALGAN® therapy for patients with these types of healthcare insurance. To contact a reimbursement specialist for conducting patient-specific insurance benefit verifications, please call the *HYALGAN® Support Hotline* at **1.866.7.HYALGAN (1.866.749.2542)**, Monday to Friday, from 9:00 AM to 8:00 PM EST.

Medicare

When HYALGAN® is injected in the hospital outpatient setting, Medicare may reimburse both the product and services associated with its administration. The payment methodology for HYALGAN® is based on its ASP plus 6%.^{*} Please note that Medicare's drug and product payment rates change on a quarterly basis. In addition, services that are associated with HYALGAN® administration would be reimbursed based on the Hospital Outpatient Prospective Payment System (HOPPS) or Ambulatory Payment Classification (APC) system. Specifically, under the APC system, each APC is associated with a fixed reimbursement amount that the hospital receives, regardless of the actual cost incurred.

Physician reimbursement in the hospital outpatient setting:

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

In general, Medicare pays 80% of the allowed amount of the drug/product and service. Medicare beneficiaries are responsible for 20% of the allowed amount of the drug/product and service once a deductible has been met. If a Medicare beneficiary has a source of secondary coverage, that insurance may be used toward this cost-sharing requirement

^{*}This allowed payment is subject to quarterly changes.

Private Payers

Private payers typically negotiate payment rates for HYALGAN® when administered in the hospital outpatient setting that may be based on a fee schedule, a percentage of billed or allowable charges, or a percentage of WAC or ASP. For each patient, cost-sharing requirements, such as coinsurance and annual deductible amounts, will vary by individual insurance plan.

Medicaid

State Medicaid programs have different payment rates for HYALGAN® when administered in the hospital outpatient setting. Specifically, payment for HYALGAN® and its associated administration services may be based on state-specific fee-for-service schedules, preset rates, or a percentage of charges. In the hospital outpatient setting, HYALGAN® may be reimbursed based on other methodologies such as a percentage of WAC or invoice price. Certain state Medicaid programs may require nominal cost-sharing by Medicaid beneficiaries for drugs/products and services.

HYALGAN® REIMBURSEMENT SUPPORT & PATIENT ASSISTANCE RESOURCES

The *HYALGAN® Support Hotline* is composed of a comprehensive reimbursement support program and a Patient Assistance Program (PAP), and is available to provide support for HYALGAN® reimbursement and access issues.

For its reimbursement support program, the *HYALGAN® Support Hotline* assists patients and healthcare providers by offering the following reimbursement and access services:

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

For its PAP, the *HYALGAN® Support Hotline* provides access to HYALGAN® in physician office and hospital outpatient settings for underinsured or uninsured patients who do not have the financial resources to pay for the product. Patients who meet the eligibility criteria may receive HYALGAN® at no charge. In order for a patient to be eligible for the HYALGAN® PAP, she or he must meet the following eligibility criteria:

- Be a legal US resident
- Must have an annual income at or below 250% of the Federal Poverty Level (FPL)
- Must not have any public or private prescription drug insurance

2021 Guidelines* For:

Persons in Family/ Household	48 Contiguous States and the District of Columbia	Alaska	Hawaii
	250% Poverty Guideline		
1	\$32,200	\$40,225	\$37,050
2	\$43,550	\$54,425	\$50,100
3	\$54,900	\$68,625	\$63,150
4	\$66,250	\$82,825	\$76,200
5	\$77,600	\$97,025	\$89,250
6	\$88,950	\$111,225	\$102,300
7	\$100,300	\$125,425	\$115,350
8	\$111,650	\$139,625	\$128,400
9+	Add \$11,350 for each additional person	Add \$14,200 for each additional person	Add \$13,050 for each additional person

Providers and patients must complete the enrollment form and submit it to the program for review. If you have a patient who may be eligible for the PAP, or if you have any questions regarding the enrollment process, please call the *HYALGAN® Support Hotline* at **1-866-7-HYALGAN (1-866-749-2542)**, Monday to Friday, from 9:00 AM to 8:00 PM EST.

Reimbursement specialists at the *HYALGAN® Support Hotline* are available to assist with questions related to reimbursement support and access services for therapy with HYALGAN®. To reach a reimbursement specialist, please call the *HYALGAN® Support Hotline* at **1-866-7-HYALGAN (1-866-749-2542)**, Monday to Friday, from 9:00 AM to 8:00 PM EST.

*SOURCE: <https://aspe.hhs.gov/poverty-guidelines>

BENEFIT VERIFICATIONS 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 HYALGAN® coverage and claims submission. Reimbursement specialists at the *HYALGAN® Support Hotline* may 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 HYALGAN® under a medical benefit or pharmacy benefit?

Does the patient's insurance plan require prior authorization for HYALGAN®?

- What information does the patient's insurance plan need for the prior authorization process?
- 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 copayment for HYALGAN® and its 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 administration of HYALGAN®?

How much does the patient's insurance plan reimburse for administration of HYALGAN® when provided in the physician office setting?

How much does the patient's insurance plan reimburse for administration of HYALGAN® when provided in the hospital outpatient setting?

For any questions you may have related to patient benefit verifications and prior authorization processes, please call the *HYALGAN® Support Hotline* at **1-866-7-HYALGAN (1-866-749-2542)**, Monday to Friday, from 9:00 AM to 8:00 PM EST.

DENIED CLAIMS AND APPEALS CHECKLIST

If a claim for HYALGAN® 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 therapy with HYALGAN®
 - Medical risks to the patient due to foregoing or delaying therapy with HYALGAN®

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 timeframe 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

For any questions you may have related to appealing denied claims, please call the *HYALGAN® Support Hotline* at **1-866-7-HYALGAN (1-866-749-2542)**, Monday to Friday, from 9:00 AM to 8:00 PM EST.

HYALGAN® SAMPLE LETTER OF MEDICAL NECESSITY

Below is a sample, template letter of medical necessity that can be customized with patient-specific information and submitted to payers. For additional assistance, please call the *HYALGAN® Support Hotline* at **1-866-7-HYALGAN (1-866-749-2542)**, Monday to Friday, from 9:00 AM to 8:00 PM EST.

Date: _____
Contact Name/Department: _____
Insurance Company: _____
Address: _____
City, State, Zip Code: _____
RE: Patient Name: _____
Date of Birth: _____
Policy/Group Number: _____

To Whom It May Concern:

I am writing this letter to support my request to treat my patient [listed above] with HYALGAN® (sodium hyaluronate) injections given at weekly intervals. I have outlined below my patient's medical history, prognosis, and treatment rationale for your review.

Summary of patient history: [include history, diagnosis, symptoms, previous and current therapies, including response to previous and current therapies]

Proposed treatment plan with HYALGAN®: [include why patient meets approved indication for HYALGAN® and summary of your professional opinion on patient's prognosis/outcome without HYALGAN®]

In summary, I believe it is medically appropriate and necessary to treat this patient with HYALGAN® at this time, and I am requesting its coverage and reimbursement. I have included the package insert for HYALGAN®, which details additional clinical information about this FDA-approved product.

Thank you for your consideration in approving this claim. Please contact me if you require any additional information.

Physician's Name: _____
Physician's Phone Number: _____

MED242-1214

HYALGAN® SAMPLE LETTER OF APPEAL

Below is a sample, template letter of appeal that may be customized with patient-specific information and submitted to payers for reconsideration of denied claims. For additional assistance, please call the *HYALGAN® Support Hotline* at **1-866-7-HYALGAN (1-866-749-2542)**, Monday to Friday, from 9:00 AM to 8:00 PM EST.

[Date]

[Name of Medical Director]

[Insurer Name]

[Address]

[City, State, Zip Code]

Re: [Patient Name]

[Patient ID Number]

[Claim Number]

Dear Dr. [Name of Medical Director]:

I am writing to formally appeal a denied claim for services provided to [insert patient's name, ID number, and claim number]. Based on a clinical assessment of my patient, the patient's diagnosis, and medical history, HYALGAN® (sodium hyaluronate) therapy is medically necessary. This letter provides my clinical rationale for HYALGAN® therapy. It presents information about this patient's medical condition and explains why it is medically necessary and appropriate for this patient.

[Insert patient's case history, including the patient's condition and clinical course prior to HYALGAN® therapy.]

Based on the clinical evidence for this case, HYALGAN® therapy is medically necessary. Accordingly, this claim should have been approved for payment.

I hope that this letter has been helpful in explaining the necessity and value of HYALGAN® therapy for this patient. I have enclosed the following documents to assist you in your reconsideration of this claim:

- A copy of the denied claim;
- Clinical literature on HYALGAN® therapy and the clinical benefits; and
- [any additional, relevant information to support the appeal, such as medical notes or payer policy].

Thank you for your reconsideration of coverage for this patient's treatment. Please call me at [insert phone number] if additional information is required.

Sincerely,

[Physician's name]



HYALGAN[®]
(sodium hyaluronate)



For full prescribing information, Visit www.HYALGAN.com.

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