



2017

Reimbursement Guide

2017 Reimbursement Guide

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 February 2017.

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

COVERAGE

REIMBURSEMENT

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, Ninth 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.

[†]ICD-9-CM will be required through September 30, 2015, though Medicare is testing ICD-10 codes March – June 2015. 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.

For products that are covered under Medicare Part B, coverage decisions are typically made through a National Coverage Determination (NCD) or a Local Coverage Determinations (LCDs). 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 LCD 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
M17.1	Unilateral 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
M17.3	Unilateral 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

HCPCS

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

HCPCS Code	Description
J7321	Hyaluronan or derivative, HYALGAN® or SUPARTZ®, for intra-articular injection, per dose NHRIC 89122-0724-20

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

Medicaid and some payers require an NHRIC code on the CMS-1500 claim form, in the shaded area 24A. Some payers require the NHRIC code to be preceded by "N4" to indicate and NHRIC code 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. 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																			
<input type="checkbox"/> PICA <input checked="" type="checkbox"/> MEDICARE <input type="checkbox"/> MEDICAID <input type="checkbox"/> TRICARE <input type="checkbox"/> CHAMPVA <input type="checkbox"/> GROUP HEALTH PLAN <input type="checkbox"/> FECA <input type="checkbox"/> OTHER										1a. INSURED'S I.D. NUMBER 123-45-6789A									
2. PATIENT'S NAME (Last Name, First Name, Middle Initial) Doe, John										4. INSURED'S NAME (Last Name, First Name, Middle Initial) Doe, John									
5. PATIENT'S ADDRESS (No., Street) 12345 Green Street										7. INSURED'S ADDRESS (No., Street) 12345 Green Street									
6. PATIENT'S BIRTH DATE MM DD YY 01 01 45										8. PATIENT STATUS Single <input type="checkbox"/> Married <input checked="" type="checkbox"/> Other <input type="checkbox"/>									
9. OTHER INSURED'S NAME (Last Name, First Name, Middle Initial)										10. IS PATIENT'S CONDITION RELATED TO:									
a. OTHER INSURED'S POLICY OR GROUP NUMBER										a. EMPLOYMENT? (Current or Previous) <input type="checkbox"/> YES <input type="checkbox"/> NO									
b. OTHER INSURED'S DATE OF BIRTH MM DD YY										b. AUTO ACCIDENT? <input type="checkbox"/> YES <input type="checkbox"/> NO									
c. EMPLOYER'S NAME OR SCHOOL NAME										c. OTHER ACCIDENT? <input type="checkbox"/> YES <input type="checkbox"/> NO									
d. INSURANCE PLAN NAME OR PROGRAM NAME										10d. RESERVED FOR LOCAL USE									
12. PATIENT'S OR AUTHORIZED PERSON'S SIGNATURE										13. INSURED'S OR AUTHORIZED PERSON'S SIGNATURE									
15. IF PATIENT HAS HAD SAME OR SIMILAR ILLNESS, GIVE FIRST DATE										16. DATES PATIENT UNABLE TO WORK IN CURRENT OCCUPATION									
17a. NPI										18. HOSPITALIZATION DATES RELATED TO CURRENT SERVICES									
21. DIAGNOSIS OR NATURE OF ILLNESS OR INJURY (Relate to ICD-10-CM)										24. A. DATE(S) OF SERVICE									
M17.1										B. PLACE OF SERVICE									
24. A. DATE(S) OF SERVICE										C. PLACE OF SERVICE									
1 MM DD 11 MM DD 11 11										24. B. CPT CODE									
1 J7321										24. C. DAYS OR UNITS									
2 MM DD 11 MM DD 11 11										24. D. DAYS OR UNITS									
2 20610 50										24. E. DAYS OR UNITS									
3										24. F. DAYS OR UNITS									
4										24. G. DAYS OR UNITS									
5										24. H. DAYS OR UNITS									
6										24. I. DAYS OR UNITS									
25. FEDERAL TAX I.D. NUMBER										26. SIGNATURE OF PHYSICIAN OR SUPPLIER									
31. SIGNATURE OF PHYSICIAN OR SUPPLIER										32. BILLING PROVIDER INFO & PH #									
25. FEDERAL TAX I.D. NUMBER										26. SIGNATURE OF PHYSICIAN OR SUPPLIER									
31. SIGNATURE OF PHYSICIAN OR SUPPLIER										32. BILLING PROVIDER INFO & PH #									

Box 21: Diagnosis Code

Enter appropriate ICD-10-CM diagnosis

Example:

M17.1—Unilateral primary osteoarthritis of knee

Box 24D: HCPCS Code

Enter HCPCS code for HYALGAN J7321—Hyaluronan or derivative, HYALGAN or SUPARTZ, 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: HYALGAN Sample Claim Form CMS-1500 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/Interpace BioPharma 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 February 2017.

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).

HCPSC Code	Description
J7321	Hyaluronan or derivative, HYALGAN or SUPARTZ, 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 change through 2017

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
M17.1	Unilateral 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
M17.3	Unilateral 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

HCPCS

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

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

On a CMS-1450/UB-04 claim form, Box 44 and Box 46 should be used for reporting HYALGAN's 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 "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 #		4 TYPE OF BILL	
				3b NEED REC #		131	
8 PATIENT NAME		9 PATIENT ADDRESS		5 FED. TAX NO.		6 STATEMENT COVERS PERIOD FROM	
Doe, John		12345 Green Street, City Town, XX, 10101				7 THROUGH	
10 BIRTH DATE	11 SEX	12 DATE	13 HR	14 TYPE	15 SRC	16 DMR	17 STAT
01/01/1945	M						
31 OCCURRENCE CODE	32 DATE	33 CODE	34 CODE	35 CODE	36 CODE	37 CODE	38 CODE
42 REV CD		43 DESCRIPTION		44 ICD-10-PCS RATE / HPCS CODE		45 SERV DATE	
0636	Drugs requiring detailed coding	J7321		MM/DD/YY		X	
0636	Clinic, general	20610 - 50		MM/DD/YY		X	
46 SERVICE UNITS		47 TOTAL CHARGES		48 NON-COVERED CHARGES		49	
Enter number of HYALGAN units administered		XXX XX		XXX XX			
Example: 1 service unit for each dose							
50 PAYER NAME		51 HEALTH PLAN ID		52 REL INFO		53 PRIOR PAYMENTS	
						54 EST. AMOUNT DUE	
55 NPI		56 NPI		57 OTHER		58 PRIV ID	
59 GROUP NAME		60 INSURANCE GROUP NO.		61 EMPLOYER NAME		62	
63 ADMIT DIX		64 PATIENT REASON DIX		65 PPS CODE		66 ECI	
67 PRINCIPAL PROCEDURE CODE		68 OTHER PROCEDURE CODE		69 OTHER PROCEDURE CODE		70 OTHER PROCEDURE CODE	
81.92							
MM/DD/YY							
71 ATTENDING		72 OPERATING		73 LAST		74 LAST	
NPI		NPI		NPI		NPI	
FIRST		FIRST		FIRST		FIRST	
LAST		LAST		LAST		LAST	
QUAL		QUAL		QUAL		QUAL	
75 ATTENDING		76 OPERATING		77 LAST		78 LAST	
NPI		NPI		NPI		NPI	
FIRST		FIRST		FIRST		FIRST	
LAST		LAST		LAST		LAST	
QUAL		QUAL		QUAL		QUAL	

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

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

Box 42: Revenue Code
Enter appropriate revenue code
Example: 0636 attached to HCPCS code J7321

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]

Box 66: Diagnosis Code
Enter appropriate ICD-10-PCS diagnosis
Example: M17.1-Unilateral primary osteoarthritis of knee

Box 74: Principal Procedure Code & Date
Enter principal ICD-10-CM procedure code and date of administration
Example: 81.92 for percutaneous knee joint injection of a therapeutic substance

DISCLAIMER: HYALGAN 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/Interpace BioPharma 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 February 2017.

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 in 2017 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 change through 2017.

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

2017 Poverty Guidelines for*:

Persons in Family/Household	48 Contiguous States and the District of Columbia	Alaska	Hawaii
	250% Poverty Guideline		
1	\$30,150	\$37,650	\$34,650
2	\$40,600	\$50,725	\$46,675
3	\$51,050	\$63,800	\$58,700
4	\$61,500	\$76,875	\$70,725
5	\$71,950	\$89,950	\$82,750
6	\$82,400	\$103,025	\$94,775
7	\$92,850	\$116,100	\$106,800
8	\$103,300	\$129,175	\$118,825
9+	Add \$10,400 for each additional person	Add \$13,075 for each additional person	Add \$12,025 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.

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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