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 2015.

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.*

<table>
<thead>
<tr>
<th>Coding System</th>
<th>Description</th>
<th>Site of Service</th>
</tr>
</thead>
<tbody>
<tr>
<td>Healthcare Common Procedure Coding System (HCPCS)</td>
<td>Alpha-numeric coding system used to report specific drugs, supplies, and other healthcare equipment used during the course of medical therapy</td>
<td>Physician office</td>
</tr>
<tr>
<td>Level II Codes</td>
<td></td>
<td>Hospital outpatient</td>
</tr>
<tr>
<td>International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) Diagnosis Codes†</td>
<td>Numeric codes used to report patient conditions, illnesses, or symptoms, which support medical necessity for need of healthcare services</td>
<td>Physician office</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Hospital outpatient</td>
</tr>
<tr>
<td>Current Procedural Terminology (CPT) Codes (HCPCS Level I Codes)</td>
<td>Numeric coding system used to report medical services and procedures related to the administration of a drug/product as provided by healthcare professionals</td>
<td>Physician office</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Hospital outpatient</td>
</tr>
<tr>
<td>Revenue Codes</td>
<td>Numeric codes used by hospitals to report on services and supplies to specific cost centers</td>
<td>Hospital outpatient</td>
</tr>
</tbody>
</table>

*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 NDCs 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.

ICD-9-CM

The ICD-9-CM diagnosis codes listed below may be appropriate to report for patients with OA of the knee who are prescribed and administered HYALGAN therapy in the physician office setting.

<table>
<thead>
<tr>
<th>ICD-9-CM Diagnosis Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>715.16</td>
<td>Osteoarthrosis, localized, primary, lower leg</td>
</tr>
<tr>
<td>715.26</td>
<td>Osteoarthrosis, localized, secondary, lower leg</td>
</tr>
<tr>
<td>715.36</td>
<td>Osteoarthrosis, localized, not specified whether primary or secondary, lower leg</td>
</tr>
<tr>
<td>715.96</td>
<td>Osteoarthrosis, unspecified whether generalized or localized, lower leg</td>
</tr>
</tbody>
</table>

On a CMS-1500 claim form, applicable ICD-9-CM diagnosis codes must be reported in Box 21.

As of October 1, 2015 Medicare will require claims to use ICD-10 replacing ICD-9. Many private payers and Medicare are testing the use of ICD-10s.

<table>
<thead>
<tr>
<th>ICD-10</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>M17.0</td>
<td>Bilateral primary osteoarthritis of knee</td>
</tr>
<tr>
<td>M17.1</td>
<td>Unilateral primary osteoarthritis of knee</td>
</tr>
<tr>
<td>M17.10</td>
<td>Unilateral primary osteoarthritis, unspecified knee</td>
</tr>
<tr>
<td>M17.11</td>
<td>Unilateral primary osteoarthritis, right knee</td>
</tr>
<tr>
<td>M17.12</td>
<td>Unilateral primary osteoarthritis, left knee</td>
</tr>
<tr>
<td>M17.2</td>
<td>Bilateral post-traumatic osteoarthritis of knee</td>
</tr>
<tr>
<td>M17.3</td>
<td>Unilateral post-traumatic osteoarthritis of knee</td>
</tr>
<tr>
<td>M17.30</td>
<td>Unilateral post-traumatic osteoarthritis, unspecified knee</td>
</tr>
<tr>
<td>M17.31</td>
<td>Unilateral post-traumatic osteoarthritis, right knee</td>
</tr>
<tr>
<td>M17.32</td>
<td>Unilateral post-traumatic osteoarthritis, left knee</td>
</tr>
<tr>
<td>M17.4</td>
<td>Other bilateral secondary osteoarthritis of knee</td>
</tr>
<tr>
<td>M17.5</td>
<td>Other unilateral secondary osteoarthritis of knee</td>
</tr>
</tbody>
</table>
**HCPCS**

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

<table>
<thead>
<tr>
<th>HCPCS Code</th>
<th>Description</th>
</tr>
</thead>
</table>
| 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:

<table>
<thead>
<tr>
<th>CPT</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>20610</td>
<td>Arthrocentesis, aspiration and/or injection; major joint or bursa (eg, shoulder, hip, knee joint, subacromial bursa), without ultrasound guidance</td>
</tr>
<tr>
<td>20611</td>
<td>Arthrocentesis, aspiration and/or injection, major joint or bursa (eg, shoulder, hip, knee, subacromial bursa); with ultrasound guidance, with permanent recording and reporting</td>
</tr>
</tbody>
</table>

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

**Box 21: Diagnosis Code**
Enter appropriate ICD-9-CM diagnosis
Example: 715.16—Osteoarthrosis, localized, primary, lower leg

**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 [e.g., 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 September 2011.
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).

While payment rates for drugs/products and administration services change, the following provides an example of Medicare’s reimbursement for HYALGAN and its administration in first-quarter 2015 when therapy is provided in the physician setting.

<table>
<thead>
<tr>
<th>HCPCS Code</th>
<th>Description</th>
<th>2015 First-Quarter Medicare Allowed Payment</th>
</tr>
</thead>
<tbody>
<tr>
<td>J7321</td>
<td>Hyaluronan or derivative, HYALGAN or SUPARTZ, for intra-articular injection, per dose</td>
<td>$90.81</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>CPT</th>
<th>Description</th>
<th>2015 Medicare National Average Payment (Non Facility)</th>
</tr>
</thead>
<tbody>
<tr>
<td>20610</td>
<td>Arthrocentesis, aspiration and/or injection; major joint or bursa (eg, shoulder, hip, knee joint, subacromial bursa), without ultrasound guidance</td>
<td>$61.41</td>
</tr>
<tr>
<td>20611</td>
<td>Arthrocentesis, aspiration and/or injection, major joint or bursa (eg, shoulder, hip, knee, subacromial bursa); with ultrasound guidance, with permanent recording and reporting</td>
<td>$93.68</td>
</tr>
</tbody>
</table>

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.
**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.HY ALGAN (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.

ICD-9-CM

The ICD-9-CM diagnosis codes listed below may be appropriate to report for patients with OA of the knee who are prescribed and administered HYALGAN therapy in the hospital outpatient setting.

<table>
<thead>
<tr>
<th>ICD-9-CM Diagnosis Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>715.16</td>
<td>Osteoarthrosis, localized, primary, lower leg</td>
</tr>
<tr>
<td>715.26</td>
<td>Osteoarthrosis, localized, secondary, lower leg</td>
</tr>
<tr>
<td>715.36</td>
<td>Osteoarthrosis, localized, not specified whether primary or secondary, lower leg</td>
</tr>
<tr>
<td>715.96</td>
<td>Osteoarthrosis, unspecified whether generalized or localized, lower leg</td>
</tr>
</tbody>
</table>

On a CMS-1450/UB-04 claim form, applicable ICD-9-CM diagnosis codes must be reported in Box 66.

As of October 1, 2015 Medicare will require claims to use ICD-10 replacing ICD-9. Many private payers and Medicare are testing the use of ICD-10s.

<table>
<thead>
<tr>
<th>ICD-10</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>M17.0</td>
<td>Bilateral primary osteoarthritis of knee</td>
</tr>
<tr>
<td>M17.1</td>
<td>Unilateral primary osteoarthritis of knee</td>
</tr>
<tr>
<td>M17.10</td>
<td>Unilateral primary osteoarthritis, unspecified knee</td>
</tr>
<tr>
<td>M17.11</td>
<td>Unilateral primary osteoarthritis, right knee</td>
</tr>
<tr>
<td>M17.12</td>
<td>Unilateral primary osteoarthritis, left knee</td>
</tr>
<tr>
<td>M17.2</td>
<td>Bilateral post-traumatic osteoarthritis of knee</td>
</tr>
<tr>
<td>M17.3</td>
<td>Unilateral post-traumatic osteoarthritis of knee</td>
</tr>
<tr>
<td>M17.30</td>
<td>Unilateral post-traumatic osteoarthritis, unspecified knee</td>
</tr>
<tr>
<td>M17.31</td>
<td>Unilateral post-traumatic osteoarthritis, right knee</td>
</tr>
<tr>
<td>M17.32</td>
<td>Unilateral post-traumatic osteoarthritis, left knee</td>
</tr>
<tr>
<td>M17.4</td>
<td>Other bilateral secondary osteoarthritis of knee</td>
</tr>
<tr>
<td>M17.5</td>
<td>Other unilateral secondary osteoarthritis of knee</td>
</tr>
</tbody>
</table>
HCPCS
To report HYALGAN administration in the hospital outpatient setting, use of HYALGAN’s permanent HCPCS code is appropriate, as noted below:

<table>
<thead>
<tr>
<th>HCPCS Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>J7321</td>
<td>Hyaluronan or derivative, HYALGAN or SUPARTZ, for intra-articular injection, per dose</td>
</tr>
</tbody>
</table>

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:

<table>
<thead>
<tr>
<th>CPT</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>20610</td>
<td>Arthrocentesis, aspiration and/or injection; major joint or bursa (eg, shoulder, hip, knee joint, subacromial bursa), without ultrasound guidance</td>
</tr>
<tr>
<td>20611</td>
<td>Arthrocentesis, aspiration and/or injection, major joint or bursa (eg, shoulder, hip, knee, subacromial bursa); with ultrasound guidance, with permanent recording and reporting</td>
</tr>
</tbody>
</table>

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.

<table>
<thead>
<tr>
<th>Revenue Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>0636</td>
<td>Drugs requiring detailed coding</td>
</tr>
<tr>
<td>0510</td>
<td>Clinic, general</td>
</tr>
</tbody>
</table>

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

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-9-CM diagnosis
Example: 715.16—Osteoarthrosis, localized, primary, lower leg

Box 74: Principal Procedure Code & Date
Enter principal ICD-9-CM procedure code and date of administration
Example: 81.92 for injection of therapeutic substance into joint or ligament

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 September 2011.
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 2012 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.

While the payment rates for drugs/products and administration services change, the following provides an example of Medicare’s reimbursement for HYALGAN and its administration in first quarter 2015 when therapy is provided in the hospital outpatient setting.

<table>
<thead>
<tr>
<th>APC</th>
<th>Description</th>
<th>2015 First Quarter Medicare Allowed Payment</th>
</tr>
</thead>
<tbody>
<tr>
<td>0204</td>
<td>Level I Nerve Injections</td>
<td>$211.13</td>
</tr>
<tr>
<td>0873</td>
<td>Hyalgan inj per dose</td>
<td>$90.81</td>
</tr>
</tbody>
</table>

Physician reimbursement in the hospital outpatient setting:

<table>
<thead>
<tr>
<th>CPT</th>
<th>Description</th>
<th>2015 Medicare National Average Payment</th>
</tr>
</thead>
<tbody>
<tr>
<td>20610</td>
<td>Arthrocentesis, aspiration and/or injection; major joint or bursa (eg, shoulder, hip, knee joint, subacromial bursa), without ultrasound guidance</td>
<td>$47.20</td>
</tr>
<tr>
<td>20611</td>
<td>Arthrocentesis, aspiration and/or injection, major joint or bursa (eg, shoulder, hip, knee, subacromial bursa); with ultrasound guidance, with permanent recording and reporting</td>
<td>$63.64</td>
</tr>
</tbody>
</table>

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.
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

2015 Poverty Guidelines for*:

<table>
<thead>
<tr>
<th>Persons in Family/Household</th>
<th>48 Contiguous States and the District of Columbia</th>
<th>Alaska</th>
<th>Hawaii</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>250% Poverty Guideline</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>$29,425</td>
<td>$36,800</td>
<td>$33,875</td>
</tr>
<tr>
<td>2</td>
<td>$39,825</td>
<td>$49,800</td>
<td>$45,825</td>
</tr>
<tr>
<td>3</td>
<td>$50,225</td>
<td>$62,800</td>
<td>$57,775</td>
</tr>
<tr>
<td>4</td>
<td>$60,625</td>
<td>$75,800</td>
<td>$69,725</td>
</tr>
<tr>
<td>5</td>
<td>$71,025</td>
<td>$88,800</td>
<td>$81,675</td>
</tr>
<tr>
<td>6</td>
<td>$81,425</td>
<td>$101,800</td>
<td>$93,625</td>
</tr>
<tr>
<td>7</td>
<td>$91,825</td>
<td>$114,800</td>
<td>$105,575</td>
</tr>
<tr>
<td>8</td>
<td>$102,225</td>
<td>$127,800</td>
<td>$117,525</td>
</tr>
<tr>
<td>For families/households with more than 8 persons</td>
<td>Add $10,400 for each additional person</td>
<td>Add $13,000 for each additional person</td>
<td>Add $11,950 for each additional person</td>
</tr>
</tbody>
</table>

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: http://aspe.hhs.gov/poverty/15poverty.cfm
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: ________________________________________________________
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 HY ALGAN (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]