**Indication**

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

**Important Safety Information**

HYMOVIS® is contraindicated in patients with known hypersensitivity to hyaluronate preparations or gram positive bacterial proteins or patients with infections/skin diseases in the area of the injection site/joint. The safety and effectiveness of HYMOVIS® has not been tested in pregnant women, nursing mothers or children. See package insert for full prescribing information including adverse events, warnings, precautions, and side effects at www.HYMOVIS.com.

**Rx Only**

See package insert for full prescribing information including indications, contraindications, warnings, precautions, and adverse events.

**Please see full Prescribing Information at www.HYMOVIS.com.**
Description and Indication

HYMOVIS® (high molecular weight viscoelastic hyaluronan) is a sterile, non-pyrogenic, viscoelastic hydrogel contained in a single-use syringe. HYMOVIS is based on an ultra-pure hyaluronan engineered using a proprietary process to increase viscosity, elasticity, and residence time without chemical crosslinking. This results in a natural hyaluronan similar to the hyaluronan found in the synovial fluid present in the human joint. The hyaluronan in HYMOVIS is derived from bacterial fermentation.

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

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

Dosage and Administration

HYMOVIS is supplied in 1 box containing 2 single-use 5 mL syringes, each containing a 3 mL dose of HYMOVIS to be injected 1 week apart. HYMOVIS is intended to be injected into the knee joint and is administered as a regimen of 2 intra-articular injections.

Using the HYMOVIS Reimbursement Guide

This guide is designed to serve healthcare professionals as a reference for general coding and claims information related to HYMOVIS. There are many factors that affect how payers will cover and pay for HYMOVIS, including the site of service where it is administered, what type of health insurance the patient has, and the type of benefits the payer offers. This guide contains the following information:

- Coding for HYMOVIS by site of service, including coding for the diagnosis and administration procedure
- HYMOVIS Support Hotline services and contact information
- Prior Authorization checklist
- Sample claim forms that illustrate the key components that may be required by a payer when completing a claim for HYMOVIS
- Tips for submitting clean claims and strategies to appeal denied claims
Information described in the HYMOVIS Reimbursement Guide is intended solely for use as a resource tool to assist physician office, hospital outpatient, and ambulatory surgical center billing staff regarding reimbursement issues. Any determination regarding if and how to seek reimbursement should be made only by the appropriate members of the staff, in consultation with the physician, and in consideration of the procedure performed or therapy provided to a specific patient. Fidia Farmaceutici S.p.A/Fidia Pharma USA Inc. does not recommend or endorse the use of any particular diagnosis or procedure code(s) and makes no determination if or how reimbursement may be available. Of important note, reimbursement codes and payment, as well as health policy and legislation, are subject to continual change; information contained in this version of the HYMOVIS Reimbursement Guide is current as of November 2016.

Information provided in the HYMOVIS Reimbursement Guide is for your guidance only. The HYMOVIS 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 HYMOVIS Support Hotline, please see the following section of the HYMOVIS Reimbursement Guide. Reimbursement specialists at the HYMOVIS Support Hotline are available to assist you with questions related to reimbursement support and access services for therapy with HYMOVIS at 1-866-HYMOVIS (1-866-496-6847), Monday through Friday, from 9:00 AM to 8:00 PM ET.
HYMOVIS Support Hotline

Coverage and coding for HYMOVIS® (high molecular weight viscoelastic hyaluronan) may vary depending on the patient’s type of health insurance and the site of service where the product is administered (ie, physician office, hospital outpatient department, or ambulatory surgical center). It will be important to conduct a benefit investigation for each patient in order to verify the following:

- Coverage and utilization restrictions, such as Prior Authorization, for HYMOVIS
- Patient copayment or coinsurance for HYMOVIS and administration services
- Coding for HYMOVIS
- Provider’s network status with plan

Upon request, the HYMOVIS Support Hotline will provide Prior Authorization support by submitting, if possible, any of the information available for a verbal Prior Authorization if the payer will accept it from the Hotline.

HYMOVIS Support Hotline offers comprehensive reimbursement assistance to practices, ambulatory surgical centers, and hospital providers. Reimbursement counselors are available to support healthcare professionals with questions and the following support services:

- Patient-specific benefit verification for medical and specialty pharmacy benefits
- Coding and billing support
- Comprehensive Prior Authorization support
- Alternative coverage research
- Claims management
- Appeals assistance
- Specialty pharmacy triage, upon request
HYMOVIS Support Hotline provides timely information to healthcare professionals in order to expedite patient access to care. In fact, most reimbursement research requests can be completed in 1 to 2 business days from the time complete information is submitted to the Hotline.

It is helpful to have the following information available when calling the Hotline to speak with a reimbursement counselor:

- Physician’s name, address, phone number, and provider number (NPI, TID, etc)
- Policy identification and group numbers
- Patient’s name, date of birth, address, and Social Security number
- Diagnosis
- Insurance company name, phone number, and fax number
- Site of care
- Name of policy holder
- Office contact name and phone number

In addition to reimbursement assistance, the HYMOVIS Support Hotline will work with you and your patients to provide additional resources that may include the following:

- Patient case management services
- Product ordering management

In order to access services available through the HYMOVIS Support Hotline, healthcare professionals and their patients are asked to fill out and sign a benefit verification request form. You can obtain the form by contacting the HYMOVIS Support Hotline, accessing it on the www.HYMOVIS.com website, or requesting one from your Fidia Pharma sales representative.

HYMOVIS Support Hotline
1-866-HYMOVIS (1-866-496-6847)
Coding for HYMOVIS® (high molecular weight viscoelastic hyaluronan) and Associated Services

Coding for HYMOVIS

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

For HYMOVIS, payers accept the following HCPCS code:

<table>
<thead>
<tr>
<th>HCPCS Code</th>
<th>Description</th>
<th>Billing Units</th>
<th>Site of Service</th>
<th>Claim Form (Location)</th>
<th>Payer Type</th>
</tr>
</thead>
<tbody>
<tr>
<td>J7322</td>
<td>Hyaluronan or derivative, HYMOVIS, for intra-articular injection, 1 mg</td>
<td>24 (1 mg = 1 billing unit Each syringe = 24 billing units)</td>
<td>Physician office</td>
<td>CMS-1500 (Box 24D)</td>
<td>All</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Hospital outpatient</td>
<td>CMS-1450 (Field 44)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Ambulatory surgical center</td>
<td>CMS-1450 (Field 44)</td>
<td></td>
</tr>
</tbody>
</table>

HYMOVIS is supplied in a 5 mL single-use syringe containing 3 mL of HYMOVIS
- Each mL has 8 mg of hyaluronan
- 3 mL has 24 mg of hyaluronan
- HYMOVIS administration does not vary by patient
  - Uniform administration for all patients

Medicare reimburses HYMOVIS at ASP+6%
Check the CMS web site for current Medicare reimbursement amounts for HYMOVIS at: [www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/McrPartBDrugAvgSalesPrice/index.html](http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/McrPartBDrugAvgSalesPrice/index.html)
Contact private payers or consult contracts for their reimbursement amounts.

National Health-Related Items Code

For devices such as HYMOVIS, the manufacturer adopts a unique, 3-segment number, known as the national health-related items code (NHRIC). Proper billing, especially to Medicare, Medicaid, or via electronic data interchange, requires the NHRIC be submitted in the 11-digit numeric 5-4-2 format (eg, 89122-0496-63). Do not use hyphens when entering the actual data on your claim. For example:

<table>
<thead>
<tr>
<th>HYMOVIS 11-digit Example</th>
<th>Reporting on CMS Claim Forms</th>
</tr>
</thead>
<tbody>
<tr>
<td>89122-0496-63</td>
<td>89122049663</td>
</tr>
</tbody>
</table>
Coding for Administration Services

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

<table>
<thead>
<tr>
<th>CPT Code</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, 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</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Modifier</th>
<th>Modifier Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>RT</td>
<td>Right side (used to identify procedures performed on the right side of the body)</td>
</tr>
<tr>
<td>LT</td>
<td>Left side (used to identify procedures performed on the left side of the body)</td>
</tr>
<tr>
<td>50</td>
<td>Bilateral procedure</td>
</tr>
</tbody>
</table>

ICD-10-CM Diagnosis Codes

International Classification of Diseases, 10th Revision, Clinical Modification (ICD-10-CM) diagnosis codes are used to report diseases and conditions. ICD-10-CM diagnosis codes identify why a patient needs treatment by documenting the medical necessity for prescribing HYMOVIS. Coding to the highest level of specificity may expedite the claims adjudication process. The following ICD-10-CM diagnosis codes may be appropriate to describe patients with OA of the knee.

<table>
<thead>
<tr>
<th>ICD-10-CM</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>M17.0</td>
<td>Bilateral 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>M17.30</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>
<tr>
<td>M17.9</td>
<td>Osteoarthritis of knee, unspecified</td>
</tr>
</tbody>
</table>

Coding for HYMOVIS may vary by payer type and plan type (ie, Medicare, private payer, Medicaid). Upon request, the HYMOVIS Support Hotline will conduct benefit verifications that provide coverage and coding information that is specific to your patient’s health insurance coverage. The Hotline program is available Monday through Friday from 9:00 AM to 8:00 PM ET at 1-866-HYMOVIS (1-866-496-6847).
# Medicare National Average Reimbursement Rate Information*

<table>
<thead>
<tr>
<th>Site of Service</th>
<th>CPT Code</th>
<th>Website for Look-up</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physician Office</td>
<td>20610</td>
<td><a href="https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PFSlooku/index.html">https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PFSlooku/index.html</a></td>
</tr>
<tr>
<td></td>
<td>20611</td>
<td></td>
</tr>
<tr>
<td>Hospital Outpatient</td>
<td>20610</td>
<td><a href="https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Addendum-A-and-Addendum-B-Updates.html">https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Addendum-A-and-Addendum-B-Updates.html</a></td>
</tr>
<tr>
<td></td>
<td>20611</td>
<td></td>
</tr>
<tr>
<td>Ambulatory Surgical Center</td>
<td>20610</td>
<td><a href="https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ASCPayment/11_Addenda_Updates.html">https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ASCPayment/11_Addenda_Updates.html</a></td>
</tr>
<tr>
<td></td>
<td>20611</td>
<td></td>
</tr>
</tbody>
</table>

*Reimbursement rates for CPT codes vary by geography; consult the CMS website for regional rates applicable to the practice or contact the local Medicare Administrative Contractor for regional rates.
The HYMOVIS Support Hotline is happy to assist you with obtaining information for prior authorization (PA) for HYMOVIS® (high molecular weight viscoelastic hyaluronan). However, if your office chooses to obtain this information without the assistance of the HYMOVIS Support Hotline, please use the checklist below to ensure that you are obtaining the information you need from your patient’s insurer.

Patient Name: ___________________________ DOB: ___________________________
Payer Name: ___________________________ Phone #: ___________________________ Date: ___________________________

<table>
<thead>
<tr>
<th>Questions to Ask</th>
<th>Answers</th>
</tr>
</thead>
<tbody>
<tr>
<td>Is a PA required?</td>
<td>☐ Yes ☐ No</td>
</tr>
<tr>
<td>What information is needed by the insurer for the PA?</td>
<td>☐ Diagnosis ☐ Previous therapy ☐ Chart notes</td>
</tr>
<tr>
<td></td>
<td>☐ Other:</td>
</tr>
<tr>
<td>Does the patient need to have a failure, contraindication, or intolerance to the following treatment options?</td>
<td>☐ Non-pharmacologic (e.g., exercise, physical therapy, weight loss if overweight)</td>
</tr>
<tr>
<td></td>
<td>☐ Intra-articular corticosteroids</td>
</tr>
<tr>
<td></td>
<td>☐ Non-steroidal anti-inflammatory medications (e.g., ibuprofen)</td>
</tr>
<tr>
<td></td>
<td>☐ Non-narcotic analgesics (e.g., acetaminophen)</td>
</tr>
<tr>
<td>Does the patient need to have documented symptomatic osteoarthritis of the knee?</td>
<td>☐ Yes ☐ No</td>
</tr>
<tr>
<td>Does the patient need to have tried any other medications for the condition?</td>
<td>☐ Yes (if yes, complete below) ☐ No</td>
</tr>
<tr>
<td>Medication/Therapy:</td>
<td>Duration of Therapy:</td>
</tr>
<tr>
<td>Does the insurer have a specific PA form?</td>
<td>☐ Yes ☐ No</td>
</tr>
<tr>
<td>If the insurer has a specific PA form, how is that form obtained (obtain website, provider portal address, and/or fax number)?</td>
<td>Online Insurer provider portal Fax</td>
</tr>
<tr>
<td>How is the PA submitted to the insurer? (obtain phone, fax, and/or portal address)</td>
<td>Phone Insurer provider portal Fax</td>
</tr>
<tr>
<td>Will the insurer provide a PA number to include on the claim form?</td>
<td>☐ Yes ☐ No</td>
</tr>
<tr>
<td>PA Number:</td>
<td></td>
</tr>
<tr>
<td>How long does it take the insurer to review the PA request?</td>
<td></td>
</tr>
<tr>
<td>Is there a required specialty pharmacy for HYMOVIS acquisition?</td>
<td>☐ Yes (if yes, complete below) ☐ No</td>
</tr>
<tr>
<td>Specialty pharmacy:</td>
<td></td>
</tr>
<tr>
<td>If a specialty pharmacy provides HYMOVIS, who obtains the PA?</td>
<td>☐ Specialty pharmacy ☐ Provider office</td>
</tr>
<tr>
<td>How long is the PA valid for HYMOVIS?</td>
<td></td>
</tr>
</tbody>
</table>

Need assistance? Contact the HYMOVIS Support Hotline. Call 1-866-HYMOVIS (1-866-496-6847) between 9 AM and 8 PM ET, Monday through Friday.
**Sample CMS-1500 Claim Form for HYMOVIS® (High Molecular Weight Viscoelastic Hyaluronan)**

This document is provided for your guidance only. Please call the HYMOVIS Support Hotline at 1-866-HYMOVIS (1-866-496-6847) to verify coding and claim information for specific payers.

**Box 21 ICD Indicator:** Identify the type of ICD diagnosis code used; (enter a “0” for ICD-10-CM)

**Box 23 Prior Authorization:** Enter the payer authorization number as obtained prior to services rendered

**Box 24G Units:** Enter the appropriate number of units of service (eg, J7322 is per 1 mg, for a syringe of HYMOVIS that is 24 units)

**Box 24D Procedures/Services/Supplies:** Enter the appropriate CPT/HCPCS codes and modifiers
- J-code: J7322 for HYMOVIS, per mg
- Administration: eg, 20610, arthrocentesis, aspiration, and/or injection, major joint or bursa, without ultrasound guidance
- Modifier: eg, LT for left knee

**Box 21 Diagnosis:** Enter the appropriate diagnosis code (eg, ICD-10-CM: M17.12, unilateral primary osteoarthritis, left knee)

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

Note: Other revenue codes may apply

Field 44: Enter appropriate CPT/HCPCS codes and Modifiers
- **Drug: J7322 HYMOVIS, for intra-articular injection, per 1 mg**
- **Administration: 20610** for knee joint injection without ultrasound guidance; Modifier **LT** (left knee) or **RT** (right knee)

Field 46: Enter the appropriate number of units of service
- Enter 24 units of **J7322** to denote use of HYMOVIS 8 mg/mL, 3 mL for 1 syringe

Field 66: Identify the type of ICD diagnosis code used
- Enter a “9” for ICD-9-CM or a “0” for ICD-10-CM

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

Note: Other diagnoses codes may apply

Field 74: Enter principal ICD-10-PCS code
- **3E0U3GC** for percutaneous knee joint injection of a therapeutic substance

This document is provided for your guidance only. Please call the HYMOVIS Support Hotline at 1-866-HYMOVIS (1-866-496-6847) to verify coding and claim information for specific payers.
The most common reasons for denied claims include:

- **Use of incorrect codes on claim**
- **Incorrect number of units reported**
- **Omission of letter of medical necessity**
- **Missing or incorrect information on claim form (e.g., misspelled patient name)**
- **Failure to obtain a PA before initiating treatment or failure to include the PA approval number on the claim form**

Since payers may have different guidelines for coding and claims filing, it is important to check with individual plans to research claims-submission requirements.

Not all payers will be familiar with HYMOVIS® (high molecular weight viscoelastic hyaluronan) since it is a newer product and billed with a its own unique HCPCS code. Payers may need more information about a product if they are unfamiliar with it and may request additional information about the patient’s treatment or diagnosis in order to determine whether a treatment is medically necessary. A letter of medical necessity may help to explain why HYMOVIS is medically necessary for the patient’s treatment. Claims for HYMOVIS may include supporting materials such as:

- Customized letter of medical necessity
- Chart notes
- Invoice
- Patient medical history
- FDA approval letter
- Prior therapies
- Package insert
Strategies to Appeal Denied Claims

If a claim for HYMOVIS® (high molecular weight viscoelastic hyaluronan) is improperly reimbursed or denied, you may consider submitting an appeal. The following list provides some tips for appealing denied claims:

- Review the explanation of benefits (EOB) to determine the reason for the denial.

- If additional information is requested, submit the necessary documentation immediately.

- Submit a corrected claim if the denial was due to a technical billing error (e.g., missing additional information associated with miscellaneous codes, incorrect patient identification number, missing diagnosis).

- Verify the appeals process with the payer.
  - Is there a particular form that must be completed?
  - Can the appeal be conducted over the phone or must it be in writing?
  - To whom should the appeal be directed?
  - What information must be included with the appeal (e.g., copy of original claim, EOB, supporting documentation)?
  - How long does the appeals process usually take?
  - How will the payer communicate the appeal decision?

- Review appeal request for accuracy, including patient identification numbers, coding, and requested information.

- Request that a specialist who is familiar with HYMOVIS review the claim for medical necessity. It is preferable to have the claim reviewed by a specialist who is presently treating patients with HYMOVIS.

- File claims appeal as soon as possible and within filing time limits.

- Reconcile claims appeal responses promptly and thoroughly to ensure appeals have been processed appropriately.

- Record appeals result (e.g., payment amount or if further action is required).

- If you have already submitted a letter of medical necessity, you should include a letter of appeal indicating why the product and/or the procedure should be covered and paid by the payer.

- Additionally, you should include a copy of the original claim and denial notification, the patient’s complete medical history, the physician’s plan for continuing treatment, and relevant journal articles supporting the use of HYMOVIS.

- If this second claim submission is denied, it may be necessary to contact the payer’s medical or claims director. Often a claim denial is reversed upon a director’s review of an accurate and complete denial appeal request.

For assistance in researching a payer’s appeal process and preparing a denial appeal, please call the HYMOVIS Support Hotline at 1-866-HYMOVIS (1-866-496-6847). A reimbursement counselor can assist you in developing an appeal strategy. We will work with your practice or patient to assist in an appeal as most appropriate.