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HYMOVIS® ONE

A unique, single-injection hyaluronic acid (HA) viscosupplement

REIMBURSEMENT GUIDE

IMPORTANT SAFETY INFORMATION

Indication

HYMOVIS® ONE 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® ONE is contraindicated in patients with known hypersensitivity (allergy) to hyaluronate preparations or gram-positive bacterial proteins. Do not administer HYMOVIS® ONE to patients with infections or skin diseases in the area of the injection site or joint. The safety and effectiveness of the use of HYMOVIS® ONE has not been tested in pregnant women, nursing mothers, or children. The safety and effectiveness of the use of HYMOVIS® ONE in joints other than the knee, or for use concomitantly with other intra-articular (IA) injections, have not been established. The effectiveness of repeat treatment cycles of HYMOVIS® ONE has not been established. Transient pain or swelling may occur after the IA injection. Transient increases in inflammation following any IA hyaluronan injection have been reported in some patients with inflammatory joint conditions. No serious adverse events or pseudoseptic reactions were reported in the HYMOVIS® ONE clinical study. The adverse events experienced and reported in the HYMOVIS® ONE clinical study were joint swelling, metatarsalgia, neck pain and headache. See package insert for full prescribing information including adverse events, warnings, precautions, and side effects at www.fidiajointcare.com/us/hymovisone.

Rx Only

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

Please see full Prescribing Information at www.fidiajointcare.com/us/hymovisone.

HYMOVIS® ONE SUPPORT HOTLINE
1-866-749-2542, option 2

The ***HYMOVIS® ONE 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***.

INTRODUCTION

Description and Indication

HYMOVIS® ONE is a sterile, non-pyrogenic, viscoelastic hydrogel contained in a single-use syringe. HYMOVIS® ONE is based on an ultra-pure hyaluronan (HA) 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® ONE is derived from bacterial fermentation.

HYMOVIS® ONE 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.fidiajointcare.com/us/hymovisone.

Dosage and Administration

HYMOVIS® ONE is supplied in a box containing 1 single-use 5 mL syringe containing a 4 mL dose of HYMOVIS® ONE. HYMOVIS® ONE is intended to be injected into the knee joint and is administered as a regimen of 1 intra-articular injection.

Using the HYMOVIS® ONE Reimbursement Guide

This guide is designed to serve healthcare professionals as a reference for general coding and claims information related to HYMOVIS® ONE. There are many factors that affect how payers will cover and pay for HYMOVIS® ONE, 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® ONE by site of service, including coding for the diagnosis and administration procedure
- ***HYMOVIS® ONE 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® ONE
- Tips for submitting clean claims and strategies to appeal denied claims

DISCLAIMER

Information described in the HYMOVIS® ONE 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 Pharma USA Inc., a wholly owned subsidiary of Fidia Farmaceutici S.p.A. (ITALY) 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® ONE Reimbursement Guide is current as of January 2026.

Information provided in the HYMOVIS® ONE Reimbursement Guide is for your guidance only. The ***HYMOVIS® ONE 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® ONE Support Hotline***, please see the following section of the HYMOVIS® ONE Reimbursement Guide. Reimbursement specialists at the ***HYMOVIS® ONE Support Hotline*** are available to assist you with questions related to reimbursement support and access services for treatment with HYMOVIS® ONE at 1-866-749-2542, option 2, Monday through Friday, from 9:00 AM to 8:00 PM ET.

OVERVIEW OF REIMBURSEMENT SUPPORT PROGRAM

HYMOVIS® ONE Support Hotline

Coverage and coding for HYMOVIS® ONE 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® ONE
- Patient copayment or coinsurance for HYMOVIS® ONE and administration services
- Coding for HYMOVIS® ONE
- Provider's network status with plan

Upon request, the ***HYMOVIS® ONE 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® ONE 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

OVERVIEW OF REIMBURSEMENT SUPPORT PROGRAM (CONT.)

HYMOVIS® ONE 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)
- Patient's name, date of birth, address, and Social Security number
- Insurance company name, phone number, and fax number
- Name of policy holder
- Policy identification and group numbers
- Diagnosis
- Site of care
- Office contact name and phone number

In addition to reimbursement assistance, the ***HYMOVIS® ONE 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® ONE 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® ONE Support Hotline***, accessing it on the www.fidiajointcare.com/us/hymovisone website, or requesting one from your Fidia Pharma USA sales representative.

HYMOVIS® ONE SUPPORT HOTLINE
1-866-749-2542, option 2

CODING FOR HYMOVIS® ONE AND ASSOCIATED SERVICES

Coding for HYMOVIS® ONE

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® ONE, payers accept the following HCPCS code:

HCPCS Code	Description	Billing Units	Site of Service	Claim Form (Location)	Payer Type
J7322	Hyaluronan or derivative, HYMOVIS® ONE, for intra-articular injection, 1 mg	**32** (1 mg = 1 billing unit Each syringe = 32 billing units)	Physician office	CMS-1500 (Box 24D)	All
			Hospital outpatient	CMS-1450 (Field 44)	
			Ambulatory surgical center	CMS-1450 (Field 44)	

HYMOVIS® ONE is supplied in a 5 mL single-use syringe containing 4 mL of HYMOVIS® ONE

- Each mL has 8 mg of hyaluronan
- 4mL of HYMOVIS® ONE has 32 mg of hyaluronan
- HYMOVIS® ONE administration does not vary by patient
  - Uniform administration of 4mL for all patients

Medicare Reimburses HYMOVIS® ONE at ASP + 6%

When HYMOVIS® ONE 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 HYMOVIS® ONE 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 HYMOVIS® ONE administration would be reimbursed based on the Medicare Physician Fee Schedule (MPFS).

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

*This allowed payment is subject to quarterly changes.

Source: https://www.cms.gov/medicare/medicare-fee-for-service-part-b-drugs/mcrpartbdrugavgsalesprice. Contact private payers or consult contracts for their reimbursement amounts.

Catalog Number (also known as the NRC*)

For devices such as HYMOVIS® ONE, the manufacturer adopts a unique, 3-segment number, known as the National Reimbursement Code (NRC)*. Proper billing, especially to Medicare, Medicaid, or via electronic data interchange, requires the catalog number be submitted in the NRC format as an 11-digit numeric 5-4-2 format (e.g., 89122-0750-01). Do not use hyphens when entering the actual data on your claim. For example:

HYMOVIS® ONE 11-digit Example	Reporting on CMS Claim Forms
89122-0750-01	89122075001

Coding for Administration Services

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

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

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

CPT codes should be reported in Box 24D of the CMS-1500 claim form. Payers may require RT, LT and 50 modifiers to be documented after CPT code. In addition, payers may require EJ, and JZ modifiers to be documented after JCode. Payers may require the JW modifier on a separate line item. See CMS JW and JZ modifiers policy FAQs for details.

*previously known as NHRIC

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® ONE. 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.

ICD-10-CM	Description
M17.0	Bilateral primary osteoarthritis of knee
M17.10	Unilateral primary osteoarthritis, unspecified knee
M17.11	Unilateral primary osteoarthritis, right knee
M17.12	Unilateral primary osteoarthritis, left knee
M17.2	Bilateral post-traumatic osteoarthritis of knee
M17.30	Unilateral post-traumatic osteoarthritis, unspecified knee
M17.31	Unilateral post-traumatic osteoarthritis, right knee
M17.32	Unilateral post-traumatic osteoarthritis, left knee
M17.14	Other bilateral secondary osteoarthritis of knee
M17.5	Other unilateral secondary osteoarthritis of knee
M17.9	Osteoarthritis of knee, unspecified

Coding for HYMOVIS® ONE may vary by payer type and plan type (i.e., Medicare, private payer, Medicaid). Upon request, the ***HYMOVIS® ONE 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 1-866-749-2542, option 2.

MEDICARE NATIONAL AVERAGE REIMBURSEMENT RATE INFORMATION*

Site of Service	CPT Code	Website for Look-up
Physician Office	20610	https://www.cms.gov/medicare/payment/part-b-drugs/asp-pricing-files
	20611	
Hospital Outpatient	20610	https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient-pps/quarterly-addenda-updates
	20611	
Ambulatory Surgical Center	20610	https://www.cms.gov/medicare/payment/prospective-payment-systems/ambulatory-surgical-center-asc/asc-payment-rates-addenda
	20611	

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

PRIOR AUTHORIZATION CHECKLIST

The ***HYMOVIS® ONE Support Hotline*** is happy to assist you with obtaining information for prior authorization (PA) for HYMOVIS® ONE . However, if your office chooses to obtain this information without the assistance of the ***HYMOVIS® ONE Support Hotline***, please use the checklist below to ensure that you are obtaining the information you need from your patient's insurer.

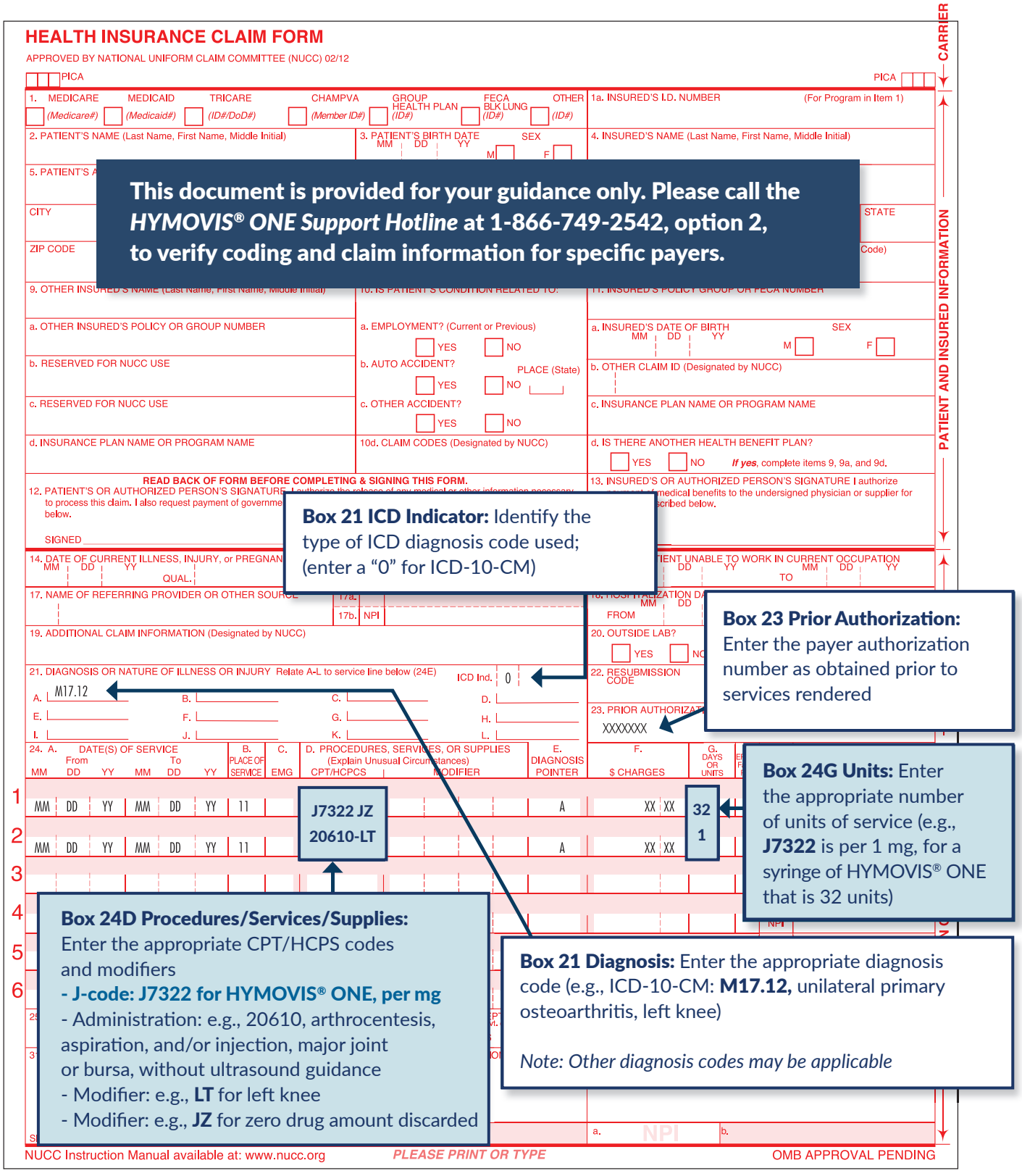
Patient Name: _____ DOB: _____

Payer Name: _____ Phone #: _____ Date: _____

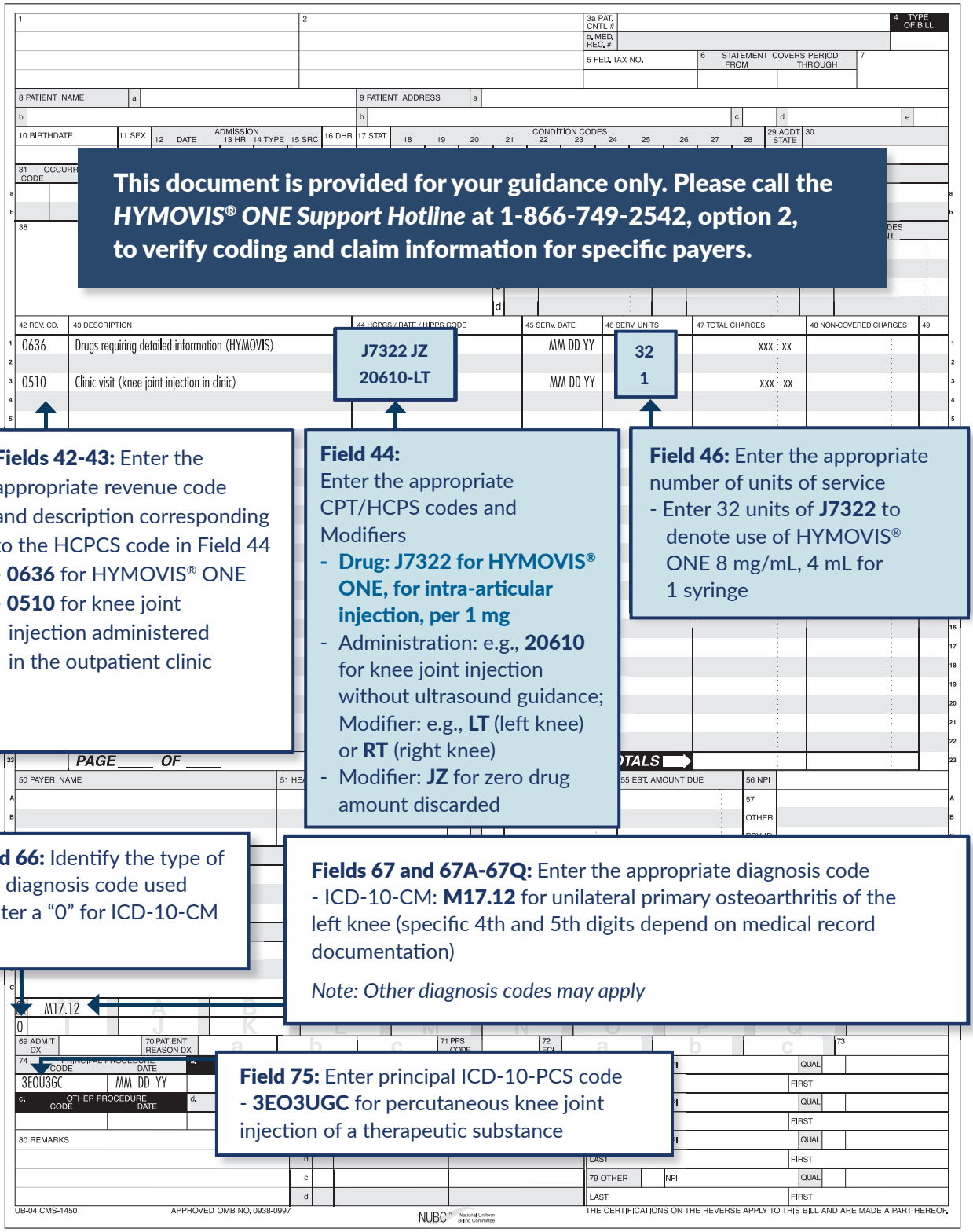
Questions to Ask	Answers		
Is a PA required?	❒ Yes	❒ No	
What information is needed by the insurer for the PA?	❒ Diagnosis ❒ Previous therapy ❒ Chart notes ❒ Other		
Does the patient need to have a failure, contraindication, or intolerance to the following treatment options?	❒ Non-pharmacologic (e.g.,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

NEED ASSISTANCE? Contact the ***HYMOVIS® ONE Support Hotline.***
Call 1-866-749-2542, option 2, between 9 AM and 8 PM ET, Monday through Friday.

SAMPLE CMS-1500 CLAIM FORM FOR HYMOVIS® ONE



SAMPLE CMS-1450 (UB-04) CLAIM FORM FOR HYMOVIS® ONE IN HOSPITAL OUTPATIENT SETTING



Fields 42-43: Enter the appropriate revenue code and description corresponding to the HCPCS code in Field 44
- **0636** for HYMOVIS® ONE
- **0510** for knee joint injection administered in the outpatient clinic

Field 44:
Enter the appropriate CPT/HCPS codes and Modifiers
- **Drug: J7322 for HYMOVIS® ONE, for intra-articular injection, per 1 mg**
- Administration: e.g., **20610** for knee joint injection without ultrasound guidance; Modifier: e.g., **LT** (left knee) or **RT** (right knee)
- Modifier: **JZ** for zero drug amount discarded

Field 46: Enter the appropriate number of units of service
- Enter 32 units of **J7322** to denote use of HYMOVIS® ONE 8 mg/mL, 4 mL for 1 syringe

Field 66: Identify the type of ICD diagnosis code used
- Enter 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 diagnosis codes may apply

Field 75: Enter principal ICD-10-PCS code
- **3EO3UGC** for percutaneous knee joint injection of a therapeutic substance

TIPS FOR CLEAN CLAIM SUBMISSION

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.

Payers may need more information about a product if they are unfamiliar with it and may ask for an additional documentation request (ADR) 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® ONE is medically necessary for the patient's treatment. Claims for HYMOVIS® ONE may include supporting materials such as:

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

Strategies to Appeal Denied Claims

If a claim for HYMOVIS® ONE 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® ONE review the claim for medical necessity. It is preferable to have the claim reviewed by a specialist who is presently treating patients with HYMOVIS® ONE

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® ONE

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® ONE Support Hotline*** at 1-866-749-2542, option 2. 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.

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SCAN TO LEARN MORE

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