

The Power of 3

(Injections for Managing Osteoarthritis (OA) Knee Pain)

REIMBURSEMENT GUIDE

IMPORTANT SAFETY INFORMATION

Indication

TRILURON® 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 and simple analgesics (e.g. acetaminophen).

Important Safety Information

Do not administer TRILURON® to patients with known hypersensitivity to hyaluronate preparations. Intraarticular injections are contraindicated in cases of past and present infections or skin diseases in the area of the injection site to reduce the potential for developing septic arthritis. The safety and effectiveness of TRILURON® 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.TRILURON.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.TRILURON.com.



The TRILURON® 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.

TRILURON® is a trademark of FIDIA FARMACEUTICI S.p.A., Abano Terme, Italy.

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INTRODUCTION

Description and Indication

TRILURON® is a viscous solution consisting of a high molecular weight (500,000–730,000 daltons) fraction of purified sodium hyaluronate (Hyalectin®) in buffered physiological sodium chloride, having a pH of 6.8-7.5. The 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 Naglucuronate-Nacetylglucosamine.

TRILURON® 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 and simple analgesics (e.g. acetaminophen).

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

Dosage and Administration

TRILURON® is supplied as a sterile, non-pyrogenic solution in 2 mL prefilled syringes. TRILURON® is administered by intra-articular injection. A treatment cycle consists of three injections given at weekly intervals. Subcutaneous lidocaine or similar local anesthetic may be recommended prior to injection of TRILURON®.

Using the TRILURON® Reimbursement Guide

This guide is designed to serve healthcare professionals as a reference for general coding and claims information related to TRILURON®. There are many factors that affect how payers will cover and pay for TRILURON®, 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 TRILURON® by site of service, including coding for the diagnosis and administration procedure

TRILURON® 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 TRILURON®

Tips for submitting clean claims and strategies to appeal denied claims



DISCLAIMER

Information described in the TRILURON® 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 FARMACEUTICIS.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 TRILURON® Reimbursement Guide is current as of January 2024.

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



OVERVIEW OF REIMBURSEMENT SUPPORT PROGRAM

TRILURON® Support Hotline

Coverage and coding for TRILURON® (sodium hyaluronate) 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 TRILURON®

Patient copayment or coinsurance for TRILURON® and administration services

Coding for TRILURON®

Provider's network status with plan

Upon request, the *TRILURON®* 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*.

TRILURON® 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.)

TRILURON® 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 *TRILURON® 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 *TRILURON® 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 *TRILURON® Support Hotline*, accessing it on the www.TRILURON.com website, or requesting one from your Fidia sales representative.





CODING FOR TRILURON® (sodium hyaluronate) AND ASSOCIATED SERVICES

Coding for TRILURON®

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 TRILURON®, payers accept the following HCPCS code:

HCPCS Code	Description	Billing Units	Site of Service	Claim Form (Location)	Payer Type
	Hyaluronan or	20	Physician Office	CMS-1500 (Box 24D)	
J7332	derivative, TRILURON® or intra-articular	(1 mg = 1 billing unit Each syringe = 20 billing units)	Hospital outpatient	CMS-1450 (Field 44)	All
	injection 1 mg	g amay	Ambulatory surgical center	CMS-1450 (Field 44)	

TRILURON® is supplied in a single-use syringe containing 2 mL of TRILURON®

- Each mL has 10 mg of sodium hyaluronate
- 2 mL has 20 mg of sodium hyaluronate
- TRILURON® administration does not vary by patient
 - Uniform administration for all patients

Medicare reimburses TRILURON® at ASP+6%

When TRILURON® 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 TRILURON® 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 TRILURON® 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

For devices such as TRILURON®, the manufacturer adopts a unique, 3-segment catalog number sometimes referred to as the national-related items code (NHRIC). Proper billing, especially to Medicare, Medicaid, or via electronic data interchange, requires the catalog number to be submitted in the 11-digit numeric 5-4-2 format (e.g. 89122-0879-01). Do not use hyphens when entering the actual data on your claim. For example:

TRILURON® 11-digit Example	Reporting on CMS Claim Forms	
89122-0879-01	89122087901	

Coding for Administration Services

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

CPT Code	Description		
20610	Arthrocentesis, aspiration, and/or injection, major joint or bursa (eg, shoulder, hip, knee, subacromial bursa); without ultrasound guidance		
20611	Arthrocentesis, aspiration, and/or injection, major joint or bursa (eg, 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 J-Code. Payers may require the JW modifier on a separate line item. See CMS JW and JZ modifiers policy FAQs for details.



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

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	
M17.4	Other bilateral secondary osteoarthritis of knee	
M17.5	Other unilateral secondary osteoarthritis of knee	
M17.9	Osteoarthritis of knee, unspecified	

Coding for TRILURON® may vary by payer type and plan type (ie, Medicare, private payer, Medicaid). Upon request, the *TRILURON® 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	20610	https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PFSlookup/index.htm	
Office	20611		
Hospital	20610	https://www.cms.gov/Medicare/Medicare-Fee-for-Service-	
Outpatient	20611	Payment/HospitalOutpatientPPS/Addendum-A-and-Addendum-B-Updates.html	
Ambulatory	20610	https://www.cms.gov/Medicare/Medicare-Fee-for-Service-	
Surgical Center	20611	Payment/ASCPayment/11 Addenda Updates.html	

^{*}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

Patient Name:_____

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

DOB:

Payer Name:	Phone #:Date:			
Questions to Ask		Ans	wers	
Is a PA required?	☐ Yes		□No	
What information is needed by the insurer for the PA?	□ Diagnosis □ F □ Other:	Previous therapy 🔲 (Chart notes	
Does the patient need to have a failure, contraindication, or intolerance to the following treatment options?	□ Non-pharmacologic (e.g. exercise, physical therapy, weight lose 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	☐ Yes (if yes, complete below)		□No	
other medications for the condition?	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	Online	Insurer provider po	rtal	Fax
that form obtained (via website, provider portal address, and/or fax number)?				
How is the PA submitted to the insurer?	Phone	Insurer provider po	rovider portal Fax	
(obtain phone, fax, and/or portal address)				
Will the insurer provide a PA number to	□Yes		□No	
include on the claim form?	PA Number:			
How long does it take the insurer to review the PA request?				
Is there a required specialty pharmacy for	☐ Yes (if yes, complete below) ☐ No			
TRILURON® acquisition?	Specialty pharmacy	<i>'</i> :		
If a specialty pharmacy provides TRILURON®, who obtains the PA?	□ Specialty pharmacy		☐ Provider office	
Lie Leavis de DA did Cartellinon@3				



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



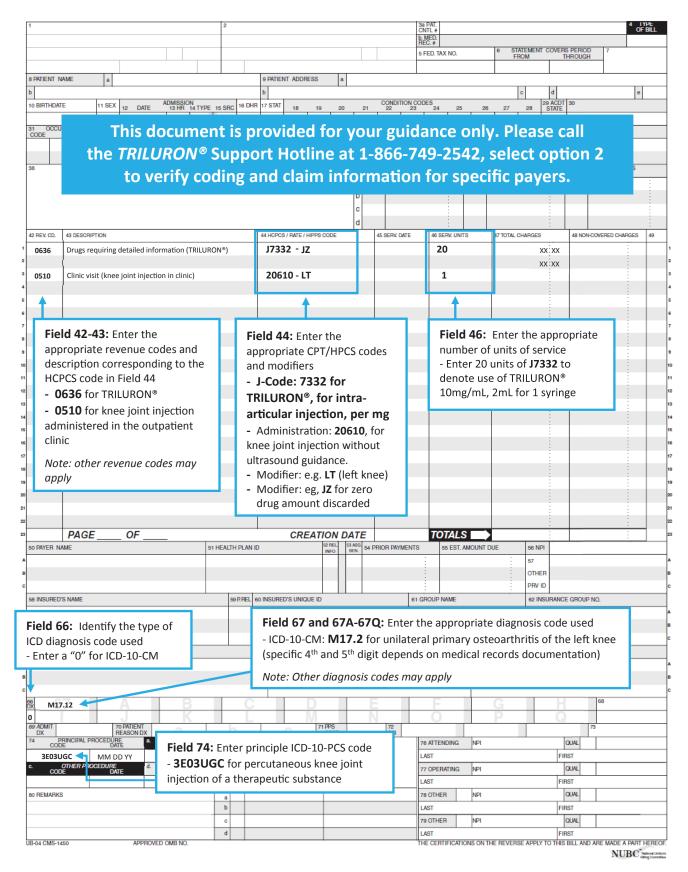
SAMPLE CMS-1500 CLAIM FORM FOR TRILURON®

(SODIUM HYALURONATE)

[발표 (사유)		
EALTH INSURANCE CLAIM FORM ROVED BY NATIONAL UNIFORM CLAIM COMMITTEE (NUCC) 02/1/2		
TIPICA		PICA
MEDICARE MEDICAID TRICARE CHAMP	- HEALTH PLAN - BLK LUNG -	1 a. INSURED'S I.D. NUMBER (For Program in Item 1)
(Medicare#) (Medicaid#) (ID#/DoD#) (Member	ID#) (ID#) (ID#) (ID#)	
This document is	provided for your gu	idance only. Please call
the TRILURON® Sup	port Hotline at 1-866	-749-2542, select option 2
taran da anti-article de la companya de la company		on for specific payers.
to verify country	and claim information	on for specific payers.
CODE TELEPHONE (Include Area Code)		ZIP CODE TELEPHONE (Include Area Code)
THER INSURED'S NAME (Last Name, First Name, Middle Initial)	10, IS PATIENT'S CONDITION RELATED TO:	11. INSURED'S POLICY GROUP OR FECA NUMBER
THE THOUSE OF TAME (Last Harris, First Harris, Middle Findar)	IS TO TAILER S CONDITION NEEDS TO.	The state of sale and state of the sale and
THER INSURED'S POLICY OR GROUP NUMBER	a. EMPLOYMENT? (Current or Previous)	a. INSURED'S DATE OF BIRTH MM DD YY
ESERVED FOR NUCC USE	b, AUTO ACCIDENT?	M F
	PLACE (State)	b. OTHER CLAIM ID (Designated by NUCC)
SERVED FOR NUCC USE	c, OTHER ACCIDENT?	c. INSURANCE PLAN NAME OR PROGRAM NAME
	YES NO	
SURANCE PLAN NAME OR PROGRAM NAME	10d. CLAIM CODES (Designated by NUCC)	d. IS THERE ANOTHER HEALTH BENEFIT PLAN? YES NO If yes, complete items 9, 9a, and 9d.
READ BACK OF FORM BEFORE		RED'S OR AUTHORIZED PERSON'S SIGNATURE I authorize
process this claim, I also request payment of government t	21 ICD Indicator: Identify the ty	ces described below.
for IC	D diagnosis code used; (enter a "0 CD-10-CM)	1982-108
	OTHER DATE	INED
M DD YY QUAL	JAL. MM DD YY	16. DATES PATIENT UNABLE TO WORK IN CURRENT OCCUPATION MM DD YY
AME OF REFERRING PROVIDER OR OTHER SOURCE	'a.	18, HOSPITALIZATION Box 23 Prior Authorization:
DDITIONAL CLAIM INFORMATION (Designated by NUCC)	b. NPI	Enter the payer authorization
BOTTOTAL OF THE PART OF THE PA		number as obtained prior to
IAGNOSIS OR NATURE OF ILLNESS OR INJURY Relate A-L to se	vice line below (24E) ICD Ind. 0	22. RESUBMISSION services rendered
M17.12 6.	D. L	And the second of the second o
F G.	н	23. PRIOR AUTHORIZATION NUMBER XXXXXXXXXX
	EDURES, SERVICES, OR SUPPLIES E.	Box 24G Units: Ente
From To PLACE OF (Exp DD YY MM DD YY SERVICE EMG CPT/HC	lain Unusual Circumstances) DIAGNOSIS PCS MODIFIER POINTER	S CHARGES DAYS OFF Plan the appropriate number of units of
	1	17222
DD	- JZ A	xx xx 20 service (e.g. J/332 is per 1 mg, for a syring
DD YY MM DD YY 11 20610	- LT	xx xx 1 of TRILURON® that is
1 1 1 1 1 1 1 1		20 units)
		NF1
Box 24D Procedures/Services/Sup		NPI
Enter the appropriate CPT/HPCS codes - J-Code: 7332 for TRILURON®, per		21 Diagnosis: Enter the appropriate diagnosis
- Administration: e.g. 20610 , arthrocer		e (e.g. ICD-10-CM: M17.12 , unilateral primary
and/or injection, major joint or bursa, v		eoarthritis, left knee)
ultrasound guidance	EPT ASSIGN	•
- Modifier: e.g. LT for left knee	.s □ N Not	e: Other diagnosis codes may be applicable
M 1161 6	: discarded	\ / /
- Modifier: eg, JZ for zero drug amount		
- Modifier: eg, JZ for zero drug amount		200
wiodiner. eg, 32 for zero drug amount		2



SAMPLE CMS-1450 (UB-04) CLAIM FORM FOR TRILURON® (SODIUM HYALURONATE) IN HOSPITAL OUTPATIENT SETTING





TIPS FOR CLEAN CLAIMS 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.

Not all payers will be familiar with TRILURON® (sodium hyaluronate) since it is a newer product and billed with 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 TRILURON® is medically necessary for the patient's treatment. Claims for TRILURON® may include supporting materials such as:



Customized letter of medical necessity



Package insert



Invoice



Patient medical history



FDA approvalletter



Prior therapies



Chart notes



Strategies to Appeal Denied Claims

If a claim for TRILURON® (sodium hyaluronate) 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 TRILURON® review the claim for medical necessity. It is preferable to have the claim reviewed by a specialist who is presently treating patients with TRILURON®

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 TRILURON®

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 *TRILURON® 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.





