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. Intra-articular 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.

TRILURON®
SUPPORT HOTLINE
1-866-749-2542, Option 2

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®
sodium hyaluronate

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-N-acetylglucosamine.

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 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 TRILURON® Reimbursement Guide is current as of October 2019.

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**

TRILURON®
sodium hyaluronate

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)**
- **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 *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.

TRILURON®
SUPPORT HOTLINE
1-866-749-2542, Option 2

TRILURON®
sodium hyaluronate

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
J7332	Hyaluronan or derivative, TRILURON® or intra-articular injection 1 mg	**20** (1 mg = 1 billing unit Each syringe = 20 billing units)	Physician Office	CMS-1500 (Box 24D)	All
			Hospital outpatient	CMS-1450 (Field 44)	
			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 WAC+6%

Source: Medicare Claims Processing Manual Chapter 17 (Rev. 4384, 08-30-19) Transmittal 20.1.3 https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c17.pdf. Contact private payers or consult contracts for their reimbursement amounts.

Catalog Number (also known as the NHRIC)

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.

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 TRILURON®. 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
M17.4	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 Office	20610	https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PFSlookup/index.html
	20611	
Hospital Outpatient	20610	https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Addendum-A-and-Addendum-B-Updates.html
	20611	
Ambulatory Surgical Center	20610	https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ASCPayment/11_Addenda_Updates.html
	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 *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.

Patient Name:_____ DOB:_____

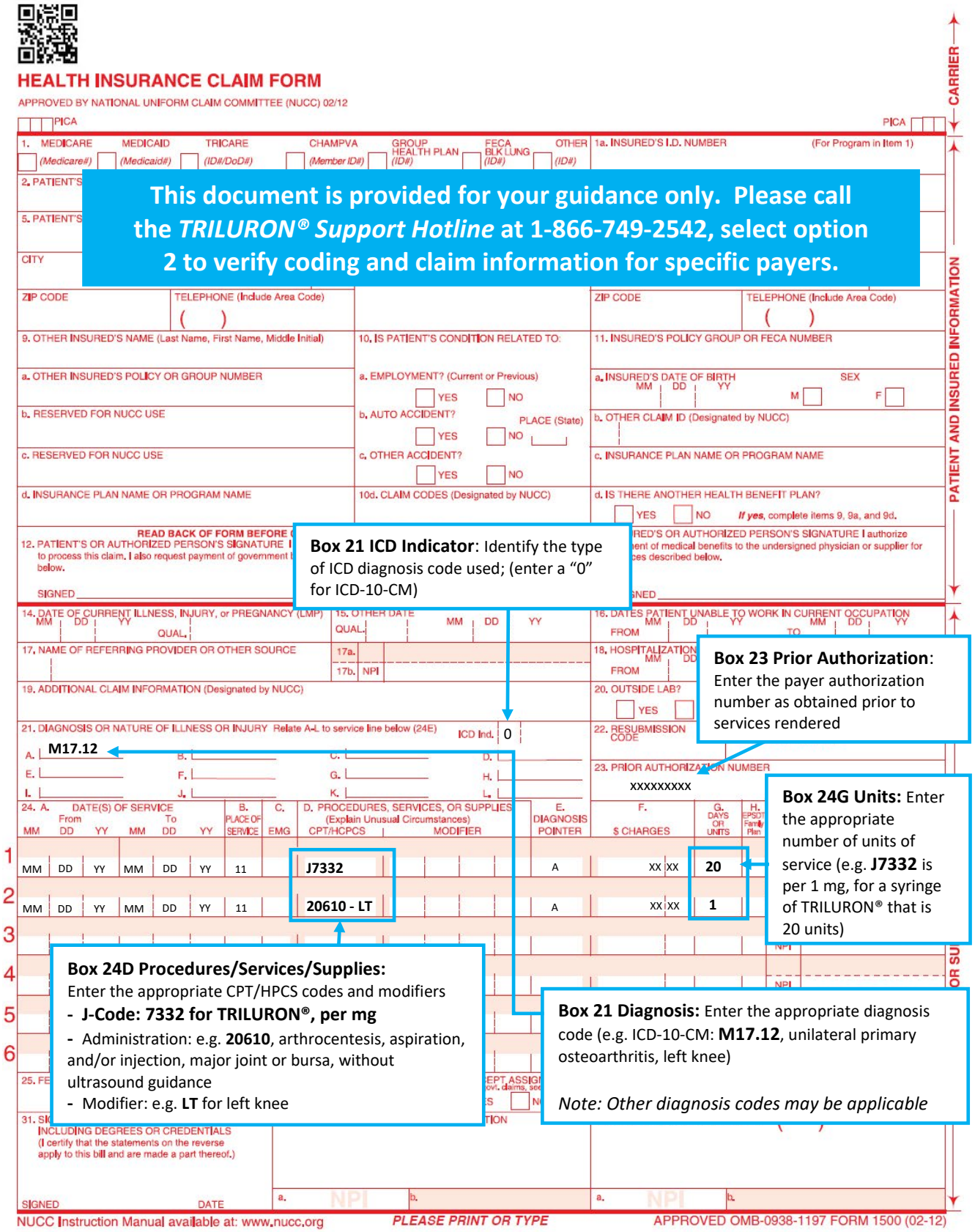
Payer Name:_____ Phone #:_____ Date: _____

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 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 other medications 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 (via 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 TRILURON® acquisition?	☐ Yes (if yes, complete below)	☐ No	
	Specialty pharmacy:		
If a specialty pharmacy provides TRILURON®, who obtains the PA?	☐ Specialty pharmacy	☐ Provider office	
How long is the PA valid for TRILURON®?			

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

TRILURON®
sodium hyaluronate

SAMPLE CMS-1500 CLAIM FORM FOR TRILURON®
(SODIUM HYALURONATE)



HEALTH INSURANCE CLAIM FORM

APPROVED BY NATIONAL UNIFORM CLAIM COMMITTEE (NUCC) 02/12

PICA

1. MEDICARE (Medicare#) | MEDICAID (Medicaid#) | TRICARE (ID#/DoD#) | CHAMPVA (Member ID#) | GROUP HEALTH PLAN (ID#) | FECA BLK LUNG (ID#) | OTHER (ID#)

1a. INSURED'S I.D. NUMBER (For Program in Item 1)

2. PATIENT'S

5. PATIENT'S

CITY

ZIP CODE | TELEPHONE (Include Area Code) ( )

ZIP CODE | TELEPHONE (Include Area Code) ( )

9. OTHER INSURED'S NAME (Last Name, First Name, Middle Initial)

10. IS PATIENT'S CONDITION RELATED TO:

11. INSURED'S POLICY GROUP OR FECA NUMBER

a. OTHER INSURED'S POLICY OR GROUP NUMBER

a. EMPLOYMENT? (Current or Previous) YES NO

a. INSURED'S DATE OF BIRTH MM DD YY SEX M F

b. RESERVED FOR NUCC USE

b. AUTO ACCIDENT? PLACE (State) YES NO

b. OTHER CLAIM ID (Designated by NUCC)

c. RESERVED FOR NUCC USE

c. OTHER ACCIDENT? YES NO

c. INSURANCE PLAN NAME OR PROGRAM NAME

d. INSURANCE 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

12. PATIENT'S OR AUTHORIZED PERSON'S SIGNATURE to process this claim. I also request payment of government below.

SIGNED

RED'S OR AUTHORIZED PERSON'S SIGNATURE I authorize ent of medical benefits to the undersigned physician or supplier for ces described below.

SIGNED

14. DATE OF CURRENT ILLNESS, INJURY, or PREGNANCY (LMP) MM DD YY QUAL.

15. OTHER DATE QUAL. MM DD YY

16. DATES PATIENT UNABLE TO WORK IN CURRENT OCCUPATION MM DD YY FROM MM DD YY TO

17. NAME OF REFERRING PROVIDER OR OTHER SOURCE

17a.

17b. NPI

18. HOSPITALIZATION MM DD FROM

19. ADDITIONAL CLAIM INFORMATION (Designated by NUCC)

20. OUTSIDE LAB? YES

21. DIAGNOSIS OR NATURE OF ILLNESS OR INJURY Relate A-L to service line below (24E) ICD Ind. 0

A. M17.12 B. C. D.

E. F. G. H.

I. J. K. L.

22. RESUBMISSION CODE

23. PRIOR AUTHORIZATION NUMBER xxxxxxxxx

24. A. DATE(S) OF SERVICE From MM DD YY	To MM DD YY	B. PLACE OF SERVICE	C. EMG	D. PROCEDURES, SERVICES, OR SUPPLIES (Explain Unusual Circumstances) CPT/HCPCS	MODIFIER	E. DIAGNOSIS POINTER	F. $ CHARGES	G. DAYS OR UNITS	H. EPSDT Family Plan	I. ID. QUAL.	J. RENDERING PROVIDER ID. #
1 MM DD YY	MM DD YY	11		J7332		A	XX XX	20			
2 MM DD YY	MM DD YY	11		20610 - LT		A	XX XX	1			
3											NPI
4											NPI
5											
6											

25. FE EPT ASSIGN ovt. claims, see S N

31. SI INCLUDING DEGREES OR CREDENTIALS (I certify that the statements on the reverse apply to this bill and are made a part thereof.) TION

SIGNED DATE

a. NPI b.

a. NPI b.

NUCC Instruction Manual available at: www.nucc.org PLEASE PRINT OR TYPE APPROVED OMB-0938-1197 FORM 1500 (02-12)

CARRIER

PATIENT AND INSURED INFORMATION

This document is provided for your guidance only. Please call the *TRILURON® Support Hotline* at 1-866-749-2542, select option 2 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 (e.g. **J7332** is per 1 mg, for a syringe of TRILURON® that is 20 units)

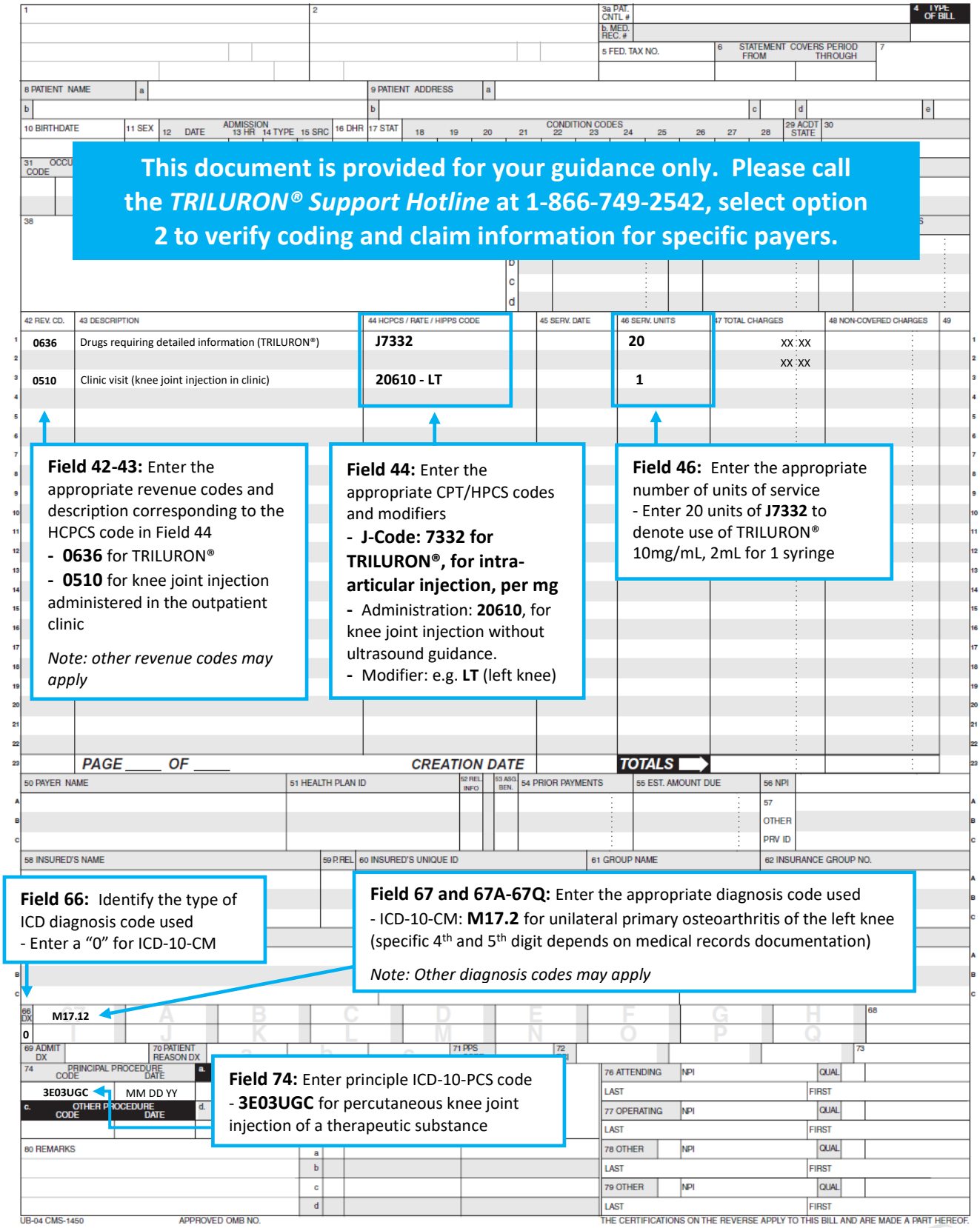
Box 24D Procedures/Services/Supplies:
Enter the appropriate CPT/HPCS codes and modifiers
- **J-Code: 7332 for TRILURON®, per mg**
- Administration: e.g. **20610**, arthrocentesis, aspiration, and/or injection, major joint or bursa, without ultrasound guidance
- Modifier: e.g. **LT** for left knee

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

Note: Other diagnosis codes may be applicable

TRILURON®
sodium hyaluronate

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



This document is provided for your guidance only. Please call the *TRILURON® Support Hotline* at 1-866-749-2542, select option 2 to verify coding and claim information for specific payers.

42 REV. CD.	43 DESCRIPTION	44 HCPCS / RATE / HIPPS CODE	45 SERV. DATE	46 SERV. UNITS	47 TOTAL CHARGES	48 NON-COVERED CHARGES
0636	Drugs requiring detailed information (TRILURON®)	J7332		20	XX XX	
					XX XX	
0510	Clinic visit (knee joint injection in clinic)	20610 - LT		1		

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

Note: other revenue codes may apply

Field 44: Enter the appropriate CPT/HPCS codes and modifiers
- **J-Code: 7332 for TRILURON®, for intra-articular injection, per mg**
- Administration: **20610**, for knee joint injection without ultrasound guidance.
- Modifier: e.g. **LT** (left knee)

Field 46: Enter the appropriate number of units of service
- Enter 20 units of **J7332** to denote use of TRILURON® 10mg/mL, 2mL for 1 syringe

Field 66: Identify the type of ICD diagnosis code used
- Enter a "0" for ICD-10-CM

Field 67 and 67A-67Q: Enter the appropriate diagnosis code used
- ICD-10-CM: **M17.2** for unilateral primary osteoarthritis of the left knee (specific 4th and 5th digit depends on medical records documentation)

Note: Other diagnosis codes may apply

Field 74: Enter principle ICD-10-PCS code
- **3E03UGC** for percutaneous knee joint injection of a therapeutic substance

TRILURON®
sodium hyaluronate

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**
- **Invoice**
- **FDA approvalletter**
- **Chart notes**
- **Package insert**
- **Patient medical history**
- **Prior therapies**

TRILURON®
sodium hyaluronate

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.

TRILURON®
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