

# FAIR AND CONSISTENT PRICING HELPS YOU MAKE THE DIFFERENCE.





3 injection hyaluronic acid regimen

trivisc.com



### Fair and Consistent Pricing Helps You Make the Difference

For osteoarthritis knee pain unresolved by non-pharmacologic therapy and simple analgesics, it's your skill that make viscosupplements work. With TriVisc you get a clinically proven 3 injection product with the advantage of fair and consistent pricing - for you and your patients.

OrthogenRx prices its products in a way that is affordable and reflective of the value they bring to patients and providers.

Reimbursement Code: J7329

#### OrthogenRx Customer Service Number: 267-753-6700 • OrthogenRx Order Fax Line: 267-753-6710 OrthogenRx Email: customerservice@orthogenrx.com • Product Code: 50653-0006-04 TriVisc.com

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#### INTRODUCTION

#### **Description and Indication**

TriVisc<sup>®</sup> is a sterile, viscoelastic non-pyrogenic solution of purified, high molecular weight sodium hyaluronate. Each 2.5 mL of TriVisc contains 10mg/ mL of sodium hyaluronate dissolved in a physiological saline. The sodium hyaluronate is derived from bacterial fermentation. Sodium hyaluronate is a poly-saccharide containing repeating disacchride units of glucuronic acid and N-acetylglucosamine. TriVisc 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.

#### **Directions for Use**

TriVisc is administered by intra-articular injection. A treatment cycle consists of three injections given at weekly intervals. Injection of subcutaneous lidocaine or similar local anesthetic may be recommended prior to injection of TriVisc.

#### Using the TriVisc Reimbursement Guide

The TriVisc Reimbursement Guide is intended to provide current and available reimbursement information related to TriVisc in the physician's office and hospital outpatient settings of care when TriVisc is administered as prescribed by a healthcare professional. In this document, coverage, coding, and payment for TriVisc are reviewed for public (Medicare) and private payers. In addition, the reimbursement support available through The Reimbursement Navigator are described. Lastly, reimbursement support tools such as sample claim forms and checklists are provided to assist healthcare providers and staff when utilizing TriVisc for patient therapy.



3 injection hyaluronic acid regimen

#### **IMPORTANT SAFETY INFORMATION**

TriVisc is indicated for the treatment of pain in osteoarthritis (OA) of the knee in patients who have failed to respond adequately to conservative nonpharmacologic therapy and to simple analgesics (eq. acetaminophen).

TriVisc is contraindicated in patients with known hypersensitivity to hyaluronate preparations. Intra-articular injections are contraindicated in cases of present infections or skin diseases in the area of the injection site to reduce the potential for developing septic arthritis.

The effectiveness of a single treatment cycle of less than 3 injections has not been established. TriVisc was established in two clinical studies of an identical chemical formulation of TriVisc. In a clinical trial of 306 patients, the frequency of adverse events was 2.9% which was identical to the frequency in the saline-control group. In the first cycle of injections the most commonly reported adverse events in the TriVisc equivalent group included injection site pain (6), allergic reaction (3), arthralgia (2), and bleeding at the injection site (2). In a clinical study involving 513 complete TriVisc equivalent treatment cycles and 487 complete PBS treatment cycles, the frequency of adverse events between the groups was the same and did not increase over the course of the three re-treatment cycles.

#### Please see Full Prescribing Information for more details.



The Reimbursement Navigator 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 Reimbursement Navigator.

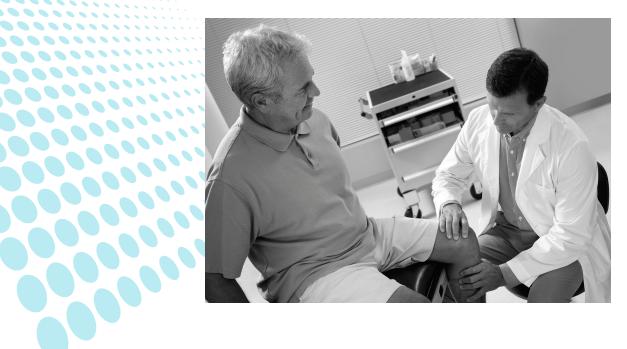
## **The Reimbursement Navigator** 866-556-2259 **Reimbursement Support Online:** orthogenrx.aspnprograms.com

#### DISCLAIMER

Information described in the TriVisc Reimbursement Guide is intended solely for use as a resource tool to assist physician office and hospital outpatient billing staff regarding reimbursement issues. Any determination regarding if and how to seek reimbursement should be made only by the appropriate members of the physician office or hospital outpatient staff, in consultation with the physician, and in consideration of the procedure performed or therapy provided to a specific patient. OrthogenRx, Inc.<sup>®</sup> 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 TriVisc Reimbursement Guide is current at the time of printing.

OrthogenRx is not responsible for failure by a physician to obtain reimbursement. Information contained in this TriVisc Reimbursement Guide is for your guidance only. The Reimbursement Navigator does not file or appeal claims for appellants, nor can it guarantee reimbursement by third-party payers. For details on the specific services provided by The Reimbursement Navigator, please see the final section of the TriVisc Reimbursement Guide.

Reimbursement specialists are available to assist you with questions related to reimbursement support and access services for therapy with TriVisc. To contact a reimbursement specialist, please call The Reimbursement Navigator at 866-556-2259, Monday to Friday, from 9:00 am to 8:00 pm EST.



#### **BASICS OF REIMBURSEMENT**

Healthcare reimbursement for medical products and services is composed of the following three (3) main elements:



#### Coverage

Coverage is a payer's determination that healthcare medications and services are medically necessary for a patient and may be included under that patient's specific insurance plan. Most payers cover therapies and their associated administration services if the product will be reimbursed for use in pain associated in OA of the knee. Typically, coverage is provided under two (2) benefit structures: the medical benefit and/or the pharmacy benefit. Both public and private payers use either medical or pharmacy benefit structures, or both.

#### Coding

Coding allows healthcare providers and payers to communicate by translating medical terminology into defined units that may be reported for appropriate reimbursement. Providers identify diseases, procedures, drugs, devices, and other healthcare-related items provided to patients through various coding systems. Payers use the same coding systems to form coverage policies and calculate payment for healthcare services.

#### Major Coding Systems – Physician office or hospital outpatient

Healthcare Common Procedure Coding System (HCPCS) Level II Codes International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) Diagnosis Codes Current Procedural Terminology (CPT)

Codes (HCPCS Level I Codes)

#### Payment

Payment is the allowed reimbursement amount that a payer provides to a healthcare provider for covered therapies and services. Typically, the payment methodology and payment amount vary based on the site of service where the care is provided. In many cases the patient is responsible for a co-pay or deductible depending on their specific policy.



Alpha-numeric coding systems are used to report specific drugs, supplies, and other healthcare equipment used during the course of medical therapy

Alpha-numeric codes are used to report patient conditions, illnesses, or symptoms, which support medical necessity for need of healthcare services

A numeric coding system is used to report medical services and procedures related to the administration of a drug/product as provided by healthcare professionals

#### **TRIVISC PUBLIC AND PRIVATE** PAYER COVERAGE INFORMATION

#### **Coverage: Medicare**

Medicare is a federally funded health insurance program that was established as part of the Social Security Act of 1965. It provides coverage to almost 50 million beneficiaries, and is administered through the following 4 benefit categories:



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Part A Hospital Insurance

Pays for inpatient hospital, skilled nursing facility, hospice, and certain home healthcare services; drugs, devices, and biologics are included within payment for Part A services when provided at covered facilities.

Covers physician-administered drugs and patient visits to

physician office and hospital outpatient settings.

Part B Medical Insurance



Part C Medicare Advantage

Administered by managed care plans, which are accountable for providing traditional Medicare services/benefits; however they have flexibility to offer additional benefits.

#### Part D Medicare Prescription Drug Coverage

Covers oral or self-administered drugs, is offered through two benefit structures, and administered by private organizations.

Medicare will reimburse healthcare providers for TriVisc when provided to a patient as a medically necessary therapy in the physician office when local carrier guidelines are followed. Because TriVisc is a physician-administered product, it is covered under Medicare Part B, and may be covered under Part C subject to commercial plan Medicare policies.

For products that are covered under Medicare Part B, coverage decisions are typically made through Local Coverage Determinations (LCDs or Articles). Medicare Administrative Contractors (MACs) generally develop LCDs or Articles. These are specific to a MAC's jurisdiction, meaning that specific coverage criteria for a product and its administration, as well as coding requirements, may vary by Medicare contractor.

Please consult your Medicare contractor to determine if any local coverage policies apply to TriVisc. To verify a patient's Medicare benefits and coverage information, please call The Reimbursement Navigator at 866-556-2259, Monday to Friday from 9:00 am to 8:00 pm EST.

### **TRIVISC PUBLIC AND PRIVATE** PAYER COVERAGE INFORMATION

#### **Coverage: Private Payers**

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Each private payer plan administers its own benefits and determines specific coverage and payment policies. Some private payers may follow Medicare's coverage policies, while other private payers may have more restrictive or less restrictive benefits. Typically, private payers will cover TriVisc when used for its FDA-approved indication. Private payers may implement restrictions such as requiring prior authorization and/or other utilization controls. Coverage may also vary significantly by the specific contracts that are negotiated between providers and private payers. Requesting plan-specific coverage information on TriVisc is an important step in understanding your patients' benefits, especially since private payer plans vary considerably.

To help verify a patient's private payer plan benefits and coverage information, please call The Reimbursement Navigator at 866-556-2259, Monday to Friday from 9:00 am to 8:00 pm EST.

#### **Coverage: Medicaid**

Each state administers its own Medicaid program; therefore, TriVisc coverage may vary from state to state. For updates on the status of Medicaid coverage for TriVisc please call The Reimbursement Navigator at 866-556-2259, Monday to Friday from 9:00 am to 8:00 pm EST.



#### TRIVISC REIMBURSEMENT IN THE PHYSICIAN OFFICE SETTING

#### Coding

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The codes relevant to TriVisc and its administration in the physician office setting are described in the following section. For more information on reporting various codes in the physician office site of care, please refer to the sample CMS-1500 claim form for TriVisc therapy on page 13.

Note: While the general codes relevant to TriVisc therapy in the physician office setting are noted in this section, other codes beyond those listed here may also be considered appropriate. As coverage for codes may vary by payer, please call **The Reimbursement Navigator** at **866-556-2259**, Monday to Friday from 9:00 am to 8:00 pm EST for assistance to verify specific or unique payer coding requirements.



#### TRIVISC REIMBURSEMENT IN THE PHYSICIAN OFFICE SETTING

#### ICD-10-CM

The ICD-10-CM diagnosis codes listed below may be appropriate to report for patients with OA of the knee and who are prescribed and administered TriVisc therapy in the physician office setting.

ICD-10-CM	
M17.0	Bilateral primary
M17.10	Unilateral prima
M17.11	Unilateral prima
M17.12	Unilateral prima
M17.2	Bilateral post-tra
M17.30	Unilateral post-
M17.31	Unilateral post-
M17.32	Unilateral post-
M17.4	Other bilateral s
M17.5	Other unilateral
M17.9	Osteoarthritis of

On a CMS-1500 claim form, applicable ICD-10-CM diagnosis codes must be reported in Box 21. Several of the above coding systems apply to other settings of care (eg, hospital inpatient, home health, pharmacy, etc.) beyond those noted above; only sites of service relevant to TriVisc and its administration are outlined here.

#### Description

y osteoarthritis of knee

ary osteoarthritis, unspecified knee

ary osteoarthritis, right knee

ary osteoarthritis, left knee

raumatic osteoarthritis of knee

traumatic osteoarthritis, unspecified knee

traumatic osteoarthritis, right knee

traumatic osteoarthritis, left knee

secondary osteoarthritis of knee

secondary osteoarthritis of knee

of knee, unspecified

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#### TRIVISC REIMBURSEMENT IN THE PHYSICIAN OFFICE SETTING

#### HCPCS

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To report the use of TriVisc in the physician office, use of TriVisc's HCPCS code is appropriate, as noted below:

HCPCS Code	Description
J7329	Hyaluronan or derivative, TriVisc for intra-articular injection, 1 mg

On a CMS-1500 claim form, Box 24D should be used for reporting the TriVisc HCPCS code.

#### CPT

To report the physician administration of TriVisc, the following CPT codes may be appropriate when TriVisc is administered in the physician office setting:

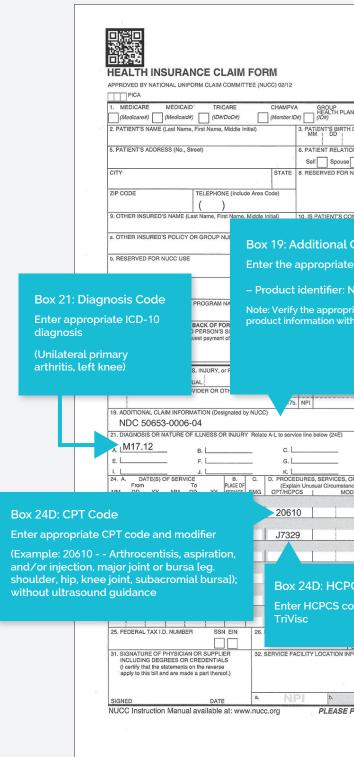
СРТ	Description
20610	Arthrocentesis, aspiration, and/or injection; major joint or bursa (eg, shoulder, hip, knee joint, subacromial bursa); without ultrasound guidance
20611	Arthocentesis, aspiration, and/or injection; major joint or bursa (eg, shoulder, hip, knee joint, subacromial bursa); with ultrasound guidance, with permanent recording and reporting

Providers are responsible for the selection of appropriate codes depending on clinical diagnosis. Information in the above table provides a general framework for understanding possible coding alternatives. It should not be used as a substitute for a healthcare professional's own judgment.

CPT codes should be reported in Box 24D of the CMS-1500 claim form as well. In certain instances, payers may require modifier "RT" (right side) or "LT" (left side) to be documented after CPT code 20610, to specify which knee was injected with TriVisc. For bilateral administration of TriVisc, some payers may require modifier "50" (bilateral procedure) to be documented after CPT code 20610 or 20611.

NDC Number: Because TriVisc, and all other HA/Viscosupplement products, are regulated as medical devices, they are not assigned NDC numbers. Instead the product code serves a similar purpose for devices as the NDC code serves for pharmaceuticals and can be used as an NDC proxy. The number for TriVisc is 50653-0006-04.

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**TRIVISC CMS-1500** SAMPLE CLAIM FORM

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FECA OTHER BLK LUNG (ID#)	1a. INSURED'S I.D. NUMB	ER	(For Program in Item 1)	╧┤┼
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M F				
Child Other	7. INSURED'S ADDRESS (	No., Street)		
	CITY		STATE	N
	ZIP CODE	TELEPHO	NE (Include Area Code)	- IATI
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IDC 50653-0006	5-04			TIEN
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The following section describes public (Medicare/Medicaid) and private payer payment information relevant to TriVisc and its administration in the physician office setting.

Note: Because of variability in payment across Medicaid and private payer plans, it is particularly important to conduct patient-specific insurance benefit verifications for TriVisc therapy for patients with these types of healthcare insurance. To contact a reimbursement specialist for help with conducting patient-specific insurance benefit verifications, please call The Reimbursement Navigator at 866-556-2259, Monday to Friday, from 9:00 am to 8:00 pm EST.

#### Medicare Fee for Service (Medicare Part B)

When TriVisc 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 TriVisc is expected to be based on Average Sales Price (ASP) + 6%. However, due to the Sequestration reimbursement may only be Average Sales Price (ASP) +4.3% (sequestration is a reduction in federal spending by a certain percentage). Please note that Medicare's drug and product payment rates may change on a quarterly basis. In addition, services that are associated with TriVisc administration would be reimbursed based on the Medicare Physician Fee Schedule. Medicare typically pays approximately 80% of this payment rate and the Medicare beneficiary is usually responsible for the remaining 20% coinsurance. Beneficiaries who purchase a Medigap plan or have other types of secondary insurance may have a portion or all of their coinsurance covered.

Providers are required to buy and bill hyaluronic acid (HA) products under traditional Fee for Service (FFS) Medicare. There is no option for a provider to obtain the product directly from a specialty pharmacy.

While payment rates may change, the following provides an example of Medicare's anticipated reimbursement for TriVisc when administered in the physician office setting.

#### PAYMENT

Medicare

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HCPCS Code	Description	Allowed Payment Rate
J7329	Hyaluronan or derivative, TriVisc for intra-articular injection, 1 mg	Published reimbursement allowable from the Medicare ASP fee schedule published each calendar quarter.
СРТ	Description	2020 Medicare National Average Payment
20610	Arthrocentesis, aspiration, ar injection; major joint or bursa (eg, shoulder, hip, knee joint, subacromial bursa); without ultrasound guidance	à
20611	Arthocentesis, aspiration, and injection; major joint or bursa (eg, shoulder, hip, knee joint, subacromial bursa); with ultra guidance, with permanent recording and reporting	A

HCPCS Code	Description	Allowed Payment Rate
J7329	Hyaluronan or derivative, TriVisc for intra-articular injection, 1 mg	Published reimbursement allowable from the Medicare ASP fee schedule published each calendar quarter.
СРТ	Description	2020 Medicare National Average Payment
20610	Arthrocentesis, aspiration, an injection; major joint or bursa (eg, shoulder, hip, knee joint, subacromial bursa); without ultrasound guidance	l .
20611	Arthocentesis, aspiration, and injection; major joint or bursa (eg, shoulder, hip, knee joint, subacromial bursa); with ultra guidance, with permanent recording and reporting	l

Providers are responsible for the selection of appropriate codes depending on clinical diagnosis. Information in the above table provides a general framework for understanding possible coding alternatives. It should not be used as a substitute for a healthcare professional's own judgment.

#### PAYMENT

#### **Private Payers**

Private payers typically negotiate payment rates for TriVisc. When administered in the physician office setting, payment may be based on a fee schedule, a percentage of billed or allowable charges, or a percentage of Average Wholesale Price (AWP), Wholesale Acquisition Cost (WAC) or ASP. For each patient, cost-sharing requirements, such as coinsurance, copayments, and annual deductible amounts, will vary by individual insurance plan.

#### Medicaid

Each state administers its own Medicaid program therefore TriVisc coverage may vary from state to state. In addition, you should confirm whether Medicaid patients have other forms of insurance. Medicaid is the payer of last resort, so in cases where patients have Medicare or other types of supplemental commercial insurance, Medicaid always pays secondary or tertiary to these payers. For updates on the status of Medicaid coverage for TriVisc please call The Reimbursement Navigator at 866-556-2259, Monday to Friday, from 9:00 am to 8:00 pm EST for assistance to verify specific or unique payer coding requirements.



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#### **TRIVISC REIMBURSEMENT SUPPORT**

#### The Reimbursement Navigator orthogenrx.aspnprograms.com

The Reimbursement Navigator is a comprehensive reimbursement support program and is available to provide support to your site of service for TriVisc reimbursement and access challenges.

#### Streamline the reimbursement and prescribing process for your TriVisc<sup>®</sup> Patients

- investigations
- Have covered prescriptions routed to an in-network pharmacy or local pharmacy to be filled
- Track TriVisc prescriptions and get current status updates

#### The Reimbursement Navigator

Speak with live support at 866-556-2259, Monday to Friday, from 9:00 am to 8:00 pm EST for assistance to verify specific or unique payer coding requirements.



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Obtain prior authorization forms for specific plans and initiate benefits



## **The Reimbursement Navigator** 866-556-2259

**Reimbursement Support Online:** orthogenrx.aspnprograms.com

TriVisc<sup>®</sup> Reimbursement Guide

#### **BENEFIT VERICATIONS AND PRIOR AUTHORIZATION CHECKLIST**

Insurance benefit verifications are recommended prior to the initiation of a patient's treatment in order to better understand his or her specific health plan benefits, and any requirements the plan may have for TriVisc coverage and claims submission. Reimbursement specialists at The Reimbursement Navigator can provide support in conducting patient-specific benefit verifications and assisting with prior authorization processes. Below is a list of information that is typically obtained through this process.



#### Does the patient's insurance plan cover TriVisc under a medical benefit or pharmacy benefit?

- Does the patient's insurance plan require prior authorization for TriVisc? • What information does the patient insurance plan need for the prior authorization request?
  - How long will the prior authorization process take?
  - Once obtained, how long will the prior authorization last before another one is required?

#### What are the patient's cost-sharing responsibilities?

- What is the patient's annual deductible? If the deductible has not yet been met in full, how much is left?
- What is the patient's maximum out-of-pocket requirement? If the maximum out-of-pocket has not yet been met in full, how much is left? • What is the patient's coinsurance or copayment for TriVisc administration?

Does the patient have other insurance coverage that needs to be coordinated with the primary source?

Does the patient's insurance plan have any coding or claims submission guidelines that must be followed for reporting TriVisc and its administration?

For any questions you may have related to patient benefit verifications and prior authorization processes, please call The Reimbursement Navigator at 866-556-2259, Monday to Friday, from 9:00 am to 8:00 pm EST.

## DENIED CLAIMS AND APPEALS CHECKLIST

If a claim for TriVisc is denied, consider the following general guidelines regarding how to review the denial, resubmit the claim form, and appeal the denial.

#### **Review the Denial**

- identify why the claim was denied:

#### **Resubmitting the Claim Form**

- highlight the following:
  - Patient's medical history

  - Medical reasons this patient was prescribed TriVisc
  - Medical risks due to delay of treatment

#### Appeal the Denial

- done as soon as possible to avoid anytimeframe limitations
- continued action is necessary
- appeals process

• Review the Explanation Of Benefits (EOB) sent by the patient's payer to

- Claims often are denied as a result of simple errors, such as missing identification numbers, patient names, or signatures; claim errors may also consist of reporting incorrect codes, modifiers, linkage, etc.

Resubmit the corrected claim form immediately after addressing any errors.

• If the reason for denial was not a result of claim submission errors, then submit a letter of medical necessity and supportive materials/literature that

- Other therapies that have been tried or were contraindicated

 If the patient's payer denies the claim again, then consider filing a grievance and reviewing the appeals process; filing a grievance or an appeal must be

Monitor payer response to appealing the denied claim and determine if

Patients or their representatives may decide to become involved in the

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To help verify a patient's insurance benefits and coverage information, please call The Reimbursement Navigator at 866-556-2259, Monday to Friday, from 9:00 am to 8:00 pm EST or enroll on-line at orthogenrx.aspnprograms.com.

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TriVisc



3 injection hyaluronic acid regimen

Distributed by: OrthogenRx,® Inc Doylestown Commerce Center 2005 S. Easton Road, Suite 207 Doylestown, PA 18901 267-753-6700



AN **AVANOS** COMPANY

Manufactured by: Meiji Pharma Spain, S.A. Avda. De Madrid 94. 28802 Alcalá de Henares (Madrid), Spain

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