Hyaluronan Derivatives for Intra-Articular Injection

NDC CODE(S)

50653-0006-XX TRIVISC 10MG/ML Solution Prefilled Syringe (ORTHOGENRX)
89130-2020-XX DUROLANE 60MG/3ML Prefilled Syringe (BIOVENTUS)
50653-0006-XX GENVISC 850 10MG/ML Solution (ORTHOGENRX, INC.)
87541-0301-XX VISCO-3 10MG/ML Solution Prefilled Syringe (ZIMMER)
50016-0957-XX VISCO-3 10MG/ML Solution Prefilled Syringe (ZIMMER)
50016-0957-XX GEL-ONE 30MG/3ML Prefilled Syringe (ZIMMER)
89122-0724-XX HYALGAN 10MG/ML Solution - vial (FIDIA PHARMACEUTICAL USA)
89122-0724-XX HYALGAN 10MG/ML Solution - syringe (FIDIA PHARMACEUTICAL USA)
89130-4444-XX SUPARTZ FX 10MG/ML Solution (BIOVENTUS)
89122-0496-XX HYMOVIS 24 MG/3ML Solution Prefilled Syringe (FIDIA PHARMACEUTICAL USA)
55566-4100-XX EUFLEXXA 20 MG/2ML Solution (FERRING)
59676-0360-XX ORTHOVISC 30MG/2ML Solution (DEPUY MITEK)
58468-0090-XX SYNVISC 16MG/2ML Solution (GENZYME)
58468-0090-XX SYNVISC ONE 48MG/6ML Solution (GENZYME)
59676-0820-XX MONOVISC 88 MG/4ML Solution (DEPUY MITEK)
89130-3111-XX GELSYN-3 8.4MG/ML Solution (BIOVENTUS)
57844-0181-XX SODIUM HYALURONATE 20MG/2ML Solution Prefilled Syringe (TEVA SELECT BRANDS)
xxxxx-xxxx-XX SYNOJOYNT 20 MG/2ML Prefilled Syringe TEVA PHARMACEUTICALS)
89122-0879-xx TRILURON 20 MG/2ML Solution (FIDIA PHARMA USA)

DESCRIPTION

Hyaluronan, also known as hyaluronic acid, is a naturally occurring glycosaminoglycan with viscoelastic properties. It is found throughout the body in the extracellular matrix of connective, epithelial and neural tissues, the umbilical cord and the aqueous and vitreous humors of the eye.

Hyaluronan derivatives for clinical use are known as hyaluronate sodium or sodium hyaluronate. They are highly purified viscoelastic solutions obtained from chicken combs or bacterial cells. Hyaluronan derivatives have been developed for use in surgery (ophthalmic and cosmetic), topical applications for wound care; however, this policy addresses only the use of hyaluronan derivatives for use in intra-articular injection or viscosupplementation.

POLICY

- Hyaluronan derivative intra-articular injection for the treatment of osteoarthritis of the knee is considered ***medically necessary*** if the medical appropriateness criteria are met. **(See Medical Appropriateness below.)**
- Hyaluronan derivative intra-articular injection for the treatment of other conditions/diseases is considered ***investigational.***

MEDICAL APPROPRIATENESS

INITIAL APPROVAL

- Hyaluronan derivative intra-articular injection is considered **medically appropriate** if **ALL** of the following criteria are met:
  - Documented diagnosis of symptomatic osteoarthritis of the knee

- Trial and failure of conservative therapy methods which has not resulted in functional improvement after at least three (3) months to **ALL** of the following:
  - Non-pharmacologic therapy with physical, psychosocial, or mind-body approach (e.g., exercise-land based or aquatic, physical therapy, tai chi, yoga, weight management, cognitive behavioral therapy, knee brace or cane, etc.)
  - Pharmacologic approach (e.g., topical non-steroidal anti-inflammatory drugs (NSAIDs), topical capsaicin, oral NSAIDs with or without oral proton pump inhibitors, COX-2 inhibitors, acetaminophen, tramadol, duloxetine, etc.)
- Failure to adequately respond to aspiration and injection of intra-articular steroids
- **BCBST Requirement**: Individual meets **ALL** of the following:
  - Has not received therapy with intra-articular long-acting corticosteroid type drugs (i.e. triamcinolone acetonide ER, etc.) within the previous 6 months of therapy
  - Individual is/has **ANY ONE** of the following:
    - Continuing treatment with requested hyaluronan derivative product
    - Documented failure, contraindication, inadequate response or intolerable side effects with prior trial of **BOTH** of the following:
      - Euflexxa®
      - Synvisc®/Synvisc® One
- Reported pain interferes with functional activities (e.g., ambulation, prolonged standing)
- Individual does not have any conditions which would preclude intra-articular injections (e.g., active joint infection, unstable joint, bleeding disorder, etc.)

RENEWAL CRITERIA

- Hyaluronan derivative intra-articular injection is considered **medically appropriate** for renewal if **ALL** of the following criteria are met:
  - Individual continues to meet initial approval criteria
  - The individual shows disease response as indicated by improvement in signs and symptoms of pain and a stabilization or improvement in functional capacity during the 6-month period following the previous series of injections as evidenced by objective measures.
  - Absence of unacceptable toxicity from the previous injections. Examples of unacceptable toxicity include: severe joint swelling and pain, severe infections, anaphylactic or anaphylactoid reactions, etc.

INDICATION(S)	**DOSAGE & ADMINISTRATION** (per knee per 180 days)
Durolane	60 mg intra-articularly x 1 administration
Euflexxa	20 mg intra-articularly once weekly x 3 administrations
Gel-One	30 mg intra-articularly x 1 administration
GelSyn-3	16.8 mg intra-articularly once weekly x 3 administrations
GenVisc 850	25 mg intra-articularly once weekly x 5 administrations
Hyalgan	20 mg intra-articularly once weekly x 5 administrations
Hymovis	24 mg intra-articularly once weekly x 2 administrations
Monovisc	88 mg intra-articularly x 1 administration
Orthovisc	30 mg intra-articularly once weekly x 4 administrations
Sodium hyaluronate	20 mg intra-articularly once weekly x 3 administrations
Supartz/Supartz FX	25 mg intra-articularly once weekly x 5 administrations
Synojoynt	20 mg intra-articularly once weekly x 3 administrations
Synvisc	16 mg intra-articularly once weekly x 3 administrations
Synvisc-One	48 mg intra-articularly x 1 administration

TriVisc	25 mg intra-articular once weekly x 3 administrations
Visco-3	25 mg intra-articularly once weekly x 3 administrations
Triluron	20 mg intra-articularly once weekly x 3 administrations

LENGTH OF AUTHORIZATION

Coverage will be provided for a period of 6 months and may be renewed.

Refer to **DOSAGE LIMITS** below

APPLICABLE TENNESSEE STATE MANDATE REQUIREMENTS

BlueCross BlueShield of Tennessee's Medical Policy complies with Tennessee Code Annotated Section 56-7-2352 regarding coverage of off-label indications of Food and Drug Administration (FDA) approved drugs when the off-label use is recognized in one of the statutorily recognized standard reference compendia or in the published peer-reviewed medical literature.

IMPORTANT REMINDER

We develop Medical Policies to provide guidance to Members and Providers. This Medical Policy relates only to the services or supplies described in it. The existence of a Medical Policy is not an authorization, certification, explanation of benefits or a contract for the service (or supply) that is referenced in the Medical Policy. For a determination of the benefits that a Member is entitled to receive under his or her health plan, the Member's health plan must be reviewed. If there is a conflict between the Medical Policy and a health plan, the express terms of the health plan will govern.

ADDITIONAL INFORMATION

For appropriate chemotherapy regimens, dosage information, contraindications, precautions, warnings, and monitoring information, please refer to one of the standard reference compendia (e.g., the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) published by the National Comprehensive Cancer Network®, Drugdex Evaluations of Micromedex Solutions at Truven Health, or The American Hospital Formulary Service Drug Information).

SOURCES

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EFFECTIVE DATE 4/2/21

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