Intra-Articular Hyaluronan Injections for Osteoarthritis of the Knee

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Products:	Medicaid
Application:	All participating hospitals and providers
Page Number(s):	1 of 6

Disclaimer

Highmark Health Options medical policy is intended to serve only as a general reference resource regarding coverage for the services described. This policy does not constitute medical advice and is not intended to govern or otherwise influence medical decisions.

POLICY STATEMENT

Highmark Health Options may provide coverage under the medical-surgical benefits of the Company's Medicaid products for medically necessary benefits.

This policy is designed to address medical necessity guidelines that are appropriate for the majority of individuals with a particular disease, illness or condition. Each person's unique clinical circumstances warrant individual consideration, based upon review of applicable medical records.

The qualifications of the policy will meet the standards of the National Committee for Quality Assurance (NCQA) and the Delaware Department of Health and Social Services (DHSS) and all applicable state and federal regulations.

DEFINITIONS

Highmark Health Options (HHO) – Managed care organization serving vulnerable populations that have complex needs and qualify for Medicaid. Highmark Health Options members include individuals and families with low income, expecting mothers, children, and people with disabilities. Members pay nothing to very little for their health coverage. Highmark Health Options currently services Delaware Medicaid: Delaware Healthy Children Program (DHCP) and Diamond State Health Plan Plus LTSS (DSHP Plus LTSS) members.

Intra-Articular Hyaluronan Injections for Osteoarthritis of the Knee – Intra-articular injections of hyaluronan (also known as sodium hyaluronate) act as lubricants to restore elasticity and viscosity to the arthritic knee. The procedure involves an arthrocentesis to aspirate the damaged synovial fluid or joint effusion if present from the knee as directed by product. Then the hyaluronan preparation is injected intra-articularly into the knee synovial capsule (if treatment is bilateral, a separate syringe is used for each knee).

POLICY POSITION

Prior authorization is required.

The following preferred hyaluronan preparations Euflexxa® (1% sodium hyaluronate), Durolane® (hyaluronic acid), Supartz™ (sodium hyaluronate), and GelSyn-3™ (hyaluronic acid) may be considered medically necessary when **ALL** of the following are met:

- The individual has documentation of diagnosis of symptomatic painful osteoarthritis of the knee and there is no evidence of inflammatory arthritis (e.g., rheumatoid arthritis); and
- There is documentation of failure to respond adequately to at least three (3) months of conservative* therapy; and
- There are no contraindications to the hyaluronan injections; and
- There is documentation that the pain interferes with functional activities (e.g., ambulation, prolonged standing); and
- Cause of pain cannot be attributed to other forms of joint disease; and
- The injections are performed by a licensed medical professional (e.g., MD, DO, PA or CRNP). Injections cannot be performed by nursing or other medical personnel.

*Conservative therapy includes the following:

- Activity modification, participation in a home exercise program implemented by a physical therapist, protective weight bearing; and
- Non-narcotic analgesics (e.g., acetaminophen, NSAIDS) at Food and Drug Administration (FDA) or compendia based recommended therapeutic doses for osteoarthritis of the knee for a period of time adequate to assess therapeutic benefit, topical external analgesic preparations including capsaicin cream applied to affected knee joint, topical anti-inflammatory preparations applied to affected knee joint; and
- Intra-articular corticosteroid injections; or
- The individual is unable to tolerate conservative therapy due to adverse side effects or other medical condition.

Quantity Limits:

Treatment with hyaluronan preparations is limited to number of injections per knee per benefit year listed below:

Euflexxa	six (6) injections	GelSyn-3	six (6) injections
Durolane	two (2) injections	Supartz	10 injections

The use of Euflexxa (1% sodium hyaluronate), Durolane (hyaluronic acid), Supartz (sodium hyaluronate), and GelSyn-3 (hyaluronic acid) for any other indication is considered not medically necessary.

The following Non-Preferred hyaluronan preparations (Hyalgan® (sodium hyaluronate), Orthovisc® (high molecular weight hyaluronan), Gel One® (cross-linked hyaluronate), Monovisc® (lightly cross-linked high molecular weight hyaluronic acid), GenVisc 850® (sodium hyaluronate), Synvisc® (hylan G-F 20), Synvisc-One® (hylan G-F 20), Hymovis® (high molecular weight viscoelastic hyaluronan)) Synojoynt™ (1% sodium hyaluronate) Triluron™ (Sodium Hyaluronate), Visco-3 (sodium hyaluronate), and generic sodium hyaluronate 1% solution for injection may be considered medically necessary when BOTH of the following are met:

- The individual has met ALL the clinical criteria requirements as stated above for the preferred injections; and
- The individual must have had an adequate* therapeutic trial and experienced a documented drug therapy failure** with all applicable preferred intra-articular hyaluronan products.

*An adequate therapeutic trial is defined as six (6) months following a complete injection series of a preferred product at FDA or compendia based recommended therapeutic doses (unless the individual experiences an intolerable adverse effect due to drug therapy within that time period).

**Drug therapy failure consists of not achieving the desired therapeutic goal, development of an intolerable adverse effect due to drug therapy, or development of a hypersensitivity reaction to the drug product. The length of therapy with the preferred product(s) and the reason(s) for drug therapy failure should be documented.

Quantity Limits

Treatment with hyaluronan preparations is limited to number of injections per knee per benefit year listed below:

Synvisc-One	two (2) injections	Gel One	two (2) injections	Monovisc hyaluronic acid)	two (2) injections
Hymovis	four (4) injections	Synvisc	six (6) injections	Synojoynt	six (6) injections
Triluron	six (6) injections	Visco-3	six (6) injections	TriVisc	six (6) injections
Orthovisc	eight (8) injections	Hyalgan	10 injections	GenVisc 850	10 injections

The use of Hyalgan (sodium hyaluronate), Orthovisc (high molecular weight hyaluronan, Gel One (cross-linked hyaluronate), Hymovis (high molecular weight viscoelastic hyaluronan), GenVisc 850 (sodium hyaluronate), Synvisc (hylan G-F 20), Synvisc-One (hylan G-F 20), Monovisc (lightly cross-linked high molecular weight hyaluronic acid) Synojoynt (1% sodium hyaluronate) Triluron (Sodium Hyaluronate), Visco-3 (sodium hyaluronate), TriVisc (sodium hyaluronate)not meeting the criteria as indicated in this policy is considered experimental/investigational and therefore non-covered because the safety and/or effectiveness of this service cannot be established by the available published peer-reviewed literature.

Repeat Treatment Cycles

An additional course of the previously approved hyaluronan preparationmay be considered medically necessary for treatment of painful osteoarthritis of the knee when **ALL** of the following are met:

- At least six (6) months must have elapsed since the previous injection or completion of the prior series of injections; **and**
- The individual and provider have elected to continue conservative/non-surgical management of the osteoarthritis (no surgery planned within six (6) months of viscosupplementation therapy); **and**
- The medical record must document a reduction in the dose of analgesics or anti-inflammatory medications in the three (3) month period following the injection series (NOTE: not required if the member requires these medications for a comorbid medical condition in addition to knee osteoarthritis); **and**
- The medical record must objectively document significant improvement in pain and functional capacity of the knee joint. (e.g., an improvement in an objective measurement of pain and/or functional status Visual Analog Scale [VAS], Western Ontario and McMaster Universities Osteoarthritis [WOMAC] Index, or other validated objective measure).

Repeat treatment cycles of Intra-Articular Hyaluronan injections for any other indication are considered not medically necessary.

Imaging guidance is considered not medically necessary when performed during intra-articular hyaluronan injections for osteoarthritis of the knee.

Covered Procedure Codes

Code	Description
20610	Arthrocentesis, aspiration and/or injection into, a major joint or bursa (e.g., shoulder, hip, knee, or subacromial bursa); without ultrasound guidance.
20611	Arthrocentesis, aspiration and/or injection into, a major joint or bursa (e.g., shoulder, hip, knee, or subacromial bursa); with ultrasound guidance, with permanent recording and reporting.
76942	Ultrasonic guidance for needle placement (e.g., biopsy, aspiration, injection, localization device), imaging supervision and interpretation.

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Hyalgan® (Sodium Hyaluronate) [package insert]. Parsippany, NJ: Fidia Pharma USA Inc. 5/2014

Supartz FXTM (sodium hyaluronate) [package insert]. Durham, NC: Bioventus LLC.

Synvisc® Hylan G-F 20 [package insert]. Ridgefield, NJ: Genzyme Biosurgery.09/2014.

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POLICY UPDATE HISTORY

10/08/2021	Approved in Medical Policy Committee
1/4/2022	Approved in QI/UM
5/24/2023	Annual review; approved in Medical Policy Committee
05/30/2023	Approved in QI/UM