Reference number(s)
5674-A

JURISDICTION SPECIFIC MEDICARE PART B

HYALURONIC ACID INJECTIONS FOR KNEE OSTEOARTHRITIS

DUROLANE (hyaluronic acid)
EUFLEXXA (1% sodium hyaluronate)
GEL-ONE (cross-linked hyaluronate)
GELSYN-3 (sodium hyaluronate 0.84%)
GENVISC 850 (sodium hyaluronate)
HYALGAN (sodium hyaluronate)
HYMOVIS (high molecular weight viscoelastic hyaluronan)
MONOVISC (high molecular weight hyaluronan)
ORTHOVISC (high molecular weight hyaluronan)
SUPARTZ FX (sodium hyaluronate)
SYNOJOYNT (1% sodium hyaluronate)
SYNVISC (hylan G-F 20)
SYNVISC ONE (hylan G-F 20)
TRILURON (sodium hyaluronate)
TRIVISC (sodium hyaluronate)
VISCO-3 (sodium hyaluronate)

POLICY

I. COVERED USES

The indications below are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

Osteoarthritis of the knee

All other indications will be assessed on an individual basis. Submissions for indications other than those enumerated in this policy should be accompanied by supporting evidence from Medicare approved compendia.

II. DOCUMENTATION

The following documentation must be available, upon request, for all submissions:

A. Medical history and physical examination that supports symptomatic osteoarthritis of the knee, and functional limitations
B. X-ray report and/or notation in the medical record that confirms the diagnosis of osteoarthritis of the knee
C. Trial of conservative therapy, or failure, or contraindication to conservative therapy must be documented in the medical record

D. The documentation must include whether one knee is being treated (and which knee is being treated) OR if both knees are being treated.
E. The frequency of injections and dosage given must be consistent with the FDA-approved labeling and must be clearly documented.
F. The response to treatment must be noted.
G. If ultrasound is used for needle guidance with the joint injection, the documentation must support that the patient's target site on the knee for needle placement may be difficult to access.
H. The procedure and related care are within the scope of practice of the physician or appropriately trained provider's licensure.

III. EXCLUSIONS

Coverage will not be provided for members with any of the following exclusions:
A. It is contraindicated with infections or skin disease in the area of the injection site or joint and considered not reasonable and necessary and not covered by Medicare.
B. It is contraindicated to administer these products if you are allergic to hyaluronate products.
C. Imaging procedures for the purpose of needle guidance that may be considered reasonable and necessary are ultrasound and fluoroscopy. The documentation must support why imaging is needed for needle guidance and insertion. Other imaging modalities (e.g., computed tomography [CT] scan, magnetic resonance imaging [MRI], arthrography) for the purpose of needle guidance and insertion will be considered not reasonable and necessary and not covered by Medicare.

IV. CRITERIA FOR APPROVAL

Osteoarthritis of the knee
Authorization of 6 months may be granted for treatment of osteoarthritis of the knee when all of the following criteria is met:
A. The member has symptomatic osteoarthritis of the knee with pain that interferes with functional activities (such as ambulation and prolonged standing).
B. The diagnosis is supported by radiographic evidence of osteoarthritis of the knee (e.g., joint space narrowing, subchondral sclerosis, osteophytes, and subchondral cysts).
C. It is not considered reasonable and necessary to use hyaluronic acid injections as the initial treatment of osteoarthritis of the knee. The member must have tried and failed at least three months of therapy or has a contraindication to both of the following conservative treatments:
    1. Non-pharmacologic therapy (e.g., physical therapy, exercise, weight management, self-management programs, knee brace, cane).
    2. Pharmacologic therapy (e.g., acetaminophen, oral or topical nonsteroidal anti-inflammatory drugs [NSAIDs], topical capsaicin).
D. The member has failed treatment with or has a contraindication to intra-articular glucocorticoid injections.

V. CONTINUATION OF THERAPY

Osteoarthritis of the knee
Authorization of 6 months may be granted for a repeat series for treatment of osteoarthritis of the knee when all of the following criteria is met:
A. The member has symptomatic osteoarthritis of the knee with pain that interferes with functional activities (such as ambulation and prolonged standing).

B. The diagnosis is supported by radiographic evidence of osteoarthritis of the knee (e.g., joint space narrowing, subchondral sclerosis, osteophytes, and subchondral cysts).
C. It is not considered reasonable and necessary to use hyaluronic acid injections as initial treatment of osteoarthritis of the knee. The member must have tried and failed at least three months of therapy or has a contraindication to both of the following conservative treatments:
    1. Non-pharmacologic therapy (e.g., physical therapy, exercise, weight management, self-management programs, knee brace, cane).
    2. Pharmacologic therapy (e.g., acetaminophen, oral or topical nonsteroidal anti-inflammatory drugs [NSAIDs], topical capsaicin).
D. The member has failed treatment with or has a contraindication to intra-articular glucocorticoid injections.
E. The symptoms of osteoarthritis have recurred after the previous hyaluronic acid treatment.
F. The member experienced improvement in pain and functional capacity following the previous series of injections. When there was no improvement in knee pain and functional improvement from a previous series of injections, a repeat series of injections will be considered not reasonable and necessary and will not be covered.
G. At least six months have elapsed since the prior series of injections. Initiation of a repeat series of injections when at least six months have not elapsed since the prior series of injections is considered not reasonable and necessary and is not covered.

VI. DOSAGE AND ADMINISTRATION

The dose and frequency of administration should be consistent with the FDA-approved labeling. Doses and frequencies that exceed the FDA-recommended dosage/frequency as per the prescribing information, are considered not reasonable and necessary and not covered by Medicare.

VII. REFERENCES

1. Hyaluronic Acid Injections for Knee Osteoarthritis LCD (L39260) Original Version. Available at: https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx. Accessed November 17, 2022.
2. Billing and Coding: Hyaluronic Acid Injections for Knee Osteoarthritis (A59030) Original Version. Available at: https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx. Accessed November 17, 2022.