

JURISDICTION SPECIFIC MEDICARE PART B

HYALURONANS

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

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.

A. The FDA-labeled and compendia supported indications are listed below:

1. Osteoarthritis of the knee
2. Osteoarthritis of the shoulder
3. Impingement syndrome of the shoulder

B. Compendial Uses – ICD-10 codes supported by the Medicare Administrative Contractor:

The list of covered ICD-10 codes is prohibitively long to include within this policy. A complete list can be found at: <https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx>.

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. Relevant medical history, physical examination, results of pertinent diagnostic tests or procedures, and history of pharmacologic therapy
- B. Medical record with name of drug administered, route of administration, and dosage
- C. For subsequent courses of hyaluronans, documentation must clearly establish reduction of member symptomatology and medication usage.

III. CRITERIA FOR APPROVAL

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A. Osteoarthritis of the knee

1. Authorization of 6 months may be granted for treatment of pain associated with osteoarthritis of the knee for the first treatment course in members who have failed to respond adequately to conservative nonpharmacologic therapy and simple analgesics.
2. Authorization of 6 months may be granted for subsequent treatment courses of osteoarthritis of the knee when all of the following criteria are met:
 - i. The medical record indicates the member experienced significant improvement in pain and functional capacity from the prior series of injections (i.e., reduction of symptomatology and medication usage).
 - ii. The last injection (in a prior course) was given at least six months ago.

B. Osteoarthritis of the shoulder

1. Authorization of 6 months may be granted for osteoarthritis of the shoulder for the first treatment course in members who have failed to respond adequately to conservative nonpharmacologic therapy and simple analgesics.
2. Authorization of 6 months may be granted for subsequent treatment of osteoarthritis of the shoulder when all of the following criteria are met:
 - i. The medical record indicates the member experienced significant improvement in pain and functional capacity from the prior series of injections (i.e., reduction of symptomatology and medication usage).
 - ii. The last injection (in a prior course) was given at least six months ago.
 - iii. The member has received only one previous course of treatment. Repeat injections for shoulder arthritis are limited to a single repeat course.

C. Impingement syndrome of the shoulder

Authorization of 3 months may be granted for treatment of subacromial impingement syndrome of the shoulder.

D. All Other Indications

Authorization of 6 months may be granted for treatment of all other approvable indications listed in LCA A52420.

IV. DOSAGE AND ADMINISTRATION

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

V. REFERENCES

1. Drugs and Biologicals LCD (L33394) Version R14. Available at: <https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx>. Accessed October 28, 2022.
2. Billing and Coding: Hyaluronans (A52420) Version R17. Available at: <https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx>. Accessed October 28, 2022.
3. Billing and Coding: Drugs and Biologicals (A52855) Version R8. Available at: <https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx>. Accessed October 28, 2022.
4. Micromedex Solutions [database online]. Ann Arbor, MI: Truven Health Analytics Inc. Updated periodically. www.micromedexsolutions.com [available with subscription]. Accessed October 28, 2022.

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