

LOCAL MEDICAL POLICY

Policy No:

99-06

MARYLAND MEDICARE PART A**Hyaluronate Polymers (Synvisc™, Hyalgan™)****Description**

Hyaluronic acid is a natural constituent of synovial fluid and cartilage. The function of hyaluronic acid is to maintain structural and functional characteristics of extracellular matrix and fluids. It may also play a role in the interactions of local immune cells. The federal Food and Drug Administration (FDA) has approved two materials, sodium hyaluronate (Hyalgan™) and hylan G-F20 (Synvisc™). These two materials are composed of various fractions of hyaluronate, for the treatment of pain associated with osteoarthritis of the knee in patients who have failed to respond adequately to conservative non-pharmacologic therapy and simple analgesics such as acetaminophen. While these two products are injected into the knee, they have been classified by the FDA as prosthetic devices and not as drugs. This policy defines coverage criteria for the injection of the knee with either Hyalgan™ or Synvisc™.

Type(s) of Bill

11X, 18X, 21X (No HCPCS required.)

13X, 71X, 73X, 74X, 75X, 83X, 85X (HCPCS required.)

Revenue Codes

- HCPCS 20610 may be billed with the following revenue codes:
36X, 49X, 51X, and 76X
- HCPCS J3490 may be billed with the following revenue codes:
250 for bill types 11X, 18X, and 21X;
636 for bill types 13X, 71X, 73X, 74X, 75X, and 85X

HCPCS Codes

20610©	Arthrocentesis, aspiration and/or injection; major joint or bursa
J3490©	Unclassified drug

Indications and Limitations of Coverage and/or Medical Necessity

Clinical studies of sodium hyaluronate and hylan G-G-20 have demonstrated that injection of these agents into the joint space of osteoarthritic knees is sometimes followed by reduction in pain and improvement in functional capacity in some patients. The effects persist for up to six months. At present, there is no evidence that these agents reverse or retard the osteoarthritic process in the injected joints. Medicare will cover the cost of the injection and the injected hyaluronate derivative for patients who meet the following clinical criteria:

- Documented symptomatic osteoarthritis of the knee, defined as:
 - § Knee pain associated with radiographic evidence of osteophytes in the knee joint, sclerosis in bone adjacent to knee or joint space narrowing;
 - § Morning stiffness of less than 30 minutes in duration or crepitus on motion of the knee.
- Pain which interferes with functional activities, such as ambulation, prolonged standing, ability to sleep;
- Lack of functional improvement following a trial of at least three months of conservative therapy, or the patient is unable to tolerate NSAID therapy because of adverse side effects;
- The pain cannot be attributed to other forms of joint disease;
- There are no contraindications to the injections; and,
- The product is approved by the FDA for intra-articular injection.

Note: Bilateral injections may be allowed if both knees meet the criteria.

Contraindications to injection of hyaluronate products include (but are not limited to):

- Active inflammatory joint disease or synovitis affecting the knees (e.g., crystal synovitis, rheumatoid arthritis);
 - Presence of infection of the target joint or skin surrounding the

proposed site of injection; and; known hypersensitivity to hyaluronic acid preparations.

The **frequency** of injections is:

- Sodium hyaluronate is typically injected as a series of five weekly injections;
- Hylan G-F-20 is typically injected as a series of three weekly injections;
- A repeat series of injections for patients who have responded to the first series may be given individual consideration by Medicare for coverage under the following circumstances:

§ The medical record objectively documents significant improvement in pain and functional capacity; or,

§ The medical record documents significant reduction in the doses of non-steroidal anti-inflammatory medications taken or reduction in the number of intra-articular steroid injections to the knees during the six month period following the injection; and,

§ At least six months have elapsed since the prior series of injections.

§ The appropriate records documenting the improvement are submitted with the claim.

ICD-9-CM Codes that Support Medical Necessity

Medicare is establishing the following limited coverage for hyaluronate polymers for the treatment of osteoarthritis.

Covered for:

715.16 Osteoarthritis, localized, primary lower leg

715.26 Osteoarthritis, localized, secondary, lower leg

715.36 Osteoarthritis, localized, not specified whether primary or secondary, lower leg

715.96 Osteoarthritis, unspecified whether generalized or localized, lower leg

Reasons for Denial

- A repeat series of injections will be denied as not reasonable and necessary; and,

- Injection of products, which are not FDA approved for the condition, will be denied as not reasonable and necessary.
- Although some studies indicate that topical application of hyaluronate polymers may be beneficial, **topical application is not covered.**

Non-covered ICD-9-CM Code(s)

All diagnoses not listed in the “ICD-9-CM codes that Support Medical Necessity” section of this policy.

Coding Guidelines

- To report these services, use the appropriate HCPCS code(s):
 - § For a unilateral injection, use HCPCS code 20610;
 - § For a bilateral injection, use HCPCS code 20610-50; and
 - § For the hyaluronate agent injected, use J3490.
- Coverage criteria must be met for these services to be reimbursed by Medicare,
- Diagnosis(es) must be present on any claim submitted, and must be coded to the highest level of specificity; and,
- The diagnosis code(s) must be representative of the patient’s condition.

Documentation Requirements

- Documentation supporting the medical necessity should be legible, maintained in the patient’s medical record, and available to Medicare upon request.
- An appropriate diagnosis code must be submitted on the claim. The patient’s medical record should indicate the signs/symptoms supporting the diagnosis and functional impairment.
- An x-ray report of the knees must be available in the event of a review.
- Medical records should reflect failure of conservative treatment such as physical therapy, and; prior failure of simple non-narcotic analgesics, including acetaminophen.

Other Comments

Manufacturer discounts on the devices must be passed on to the Medicare Program.

Medicare will continue to monitor the utilization of this procedure through the Focused Medical Review (FMR) process.

IAC Notes

This policy does not reflect the sole opinion of the intermediary and carrier Medical Directors. Although the final decision rests with the intermediary, this policy was developed in cooperation with the Medicare Part B carrier.

Sources of Information

- TrailBlazer Health Enterprises, Inc.,[®] Special Medicare Part B Newsletter, No. 025, June 1, 1998, No. 028 October 9, 1998.
- Texas, Medicare Part A LMRP Newsletter, No. 3-98, October 22, 1998

Start Date of Comment Period

March 26, 1999.

Start Date of Notice Period

July 28, 1999.

Effective Date

Thirty (30) days from the date of this newsletter.

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