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Contractor's Policy Number

99-06-R6

Contractor's Name

CareFirst of Maryland Inc., Medicare Part A

Contractor Number

00190

Contractor Type

Fiscal Intermediary

LMRP Title

Hyaluronate Polymers (Synvisc□, Hyalgan□, Orthovisc□)

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CMS National Coverage Policy

- Establishment of national policy supersedes all previous contractor policy statements, including Local Medical Policy coverage guidelines
- Title XVIII of the Social Security Act, section 1862 (a) (7). This section excludes routine physical examinations.
- Title XVIII of the Social Security Act, section 1862 (a) (1) (A). This section allows coverage and payment for only those services that are considered to be medically reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.

Primary Geographic Jurisdiction

Maryland

Washington, DC

Secondary Geographic Jurisdiction

Alabama, Arkansas, California, Colorado, Connecticut, Delaware, Florida, Georgia, Illinois, Iowa, Kansas, Kentucky, Louisiana, Maine, Massachusetts, Michigan, Missouri, Nebraska, Nevada, New Jersey, New Mexico, New York, North Carolina, North Dakota, Ohio, Oklahoma, Pennsylvania, South Carolina, South Dakota, Tennessee, Texas, Utah, Virginia, Wisconsin, Washington state, and Wyoming

CMS Region

Region III

CMS Consortium

Northeast

Original Policy Effective Date

08/27/1999

Original Policy Ending Date

NA

Revision Effective Date

10/01/2003

Revision Ending Date

09/30/2003

LMRP 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 three materials, sodium hyaluronate (Hyalgan[®]), hylan G-F-20 (Synvisc[®]) and high molecular weight hyaluronan (Orthovisc[®]). These three 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 three 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□, Synvisc□, or Orthovisc□.

Indications and Limitations of Coverage and/or Medical Necessity

- Clinical studies of sodium hyaluronate, hylan G-F-20 and high molecular weight hyaluronan 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 the 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 in injection; and,
 - Known hypersensitivity to hyaluronic acid preparations.
- The **frequency** of injection 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;
 - High Molecular Weight Hyaluronan is typically injected in a series of three or four 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.

CPT/HCPCS Section & Benefit Category

Surgery/Musculoskeletal System

Level II HCPCS Codes

Type of Bill Code

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 J7317 and J7320 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, 83X, 85X
- HCPC 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, 83X, 85X

CPT/HCPCS Codes

The AMA and CMS require the use of short descriptors for policies published on the Web. Refer to the CPT book for the long description of the following codes:

20610© Drain/inject, joint or bursa
J7317 Sodium Hyaluronate, 20-25 mg
J7320 Hylan G-F-20, 16 mg injection
J3490 Unclassified Drugs (High Molecular Weight Hyaluronan, 30 mg. injection).

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Not Otherwise Classified (NOC)

N/A

ICD-9 Codes that Support Medical Necessity

ICD-9-CM code listings may cover a range and include truncated codes. It is the provider's responsibility to avoid truncated codes by selecting a code(s) carried out to the highest level of specificity and selected from the ICD-9-CM book appropriate to the year in which the claim is submitted.

It is not enough to link the procedure code to a correct, payable ICD-9-CM code. The diagnosis or clinical suspicion must be present for the procedure to be paid.

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

Diagnoses that Support Medical Necessity

As listed in the ICD-9 Codes that Support Medical Necessity section of this policy

ICD-9 Codes that DO NOT Support Medical Necessity

Any diagnosis codes not listed in the □ICD-9 Codes that Support Medical Necessity□ section of this policy

Diagnoses that DO NOT Support Medical Necessity

Conditions not listed in the □ICD-9 Codes that Support Medical Necessity□ section of this policy.

Reasons for Denial

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

Any diagnosis codes not listed in the □ICD-9 Codes that Support Medical Necessity□ section of this policy

Non-covered Diagnoses

Conditions not listed in the □ICD-9 Codes that Support Medical Necessity□ section of this policy.

Coding Guidelines

- To report these services, use the appropriate HCPCS code(s):
 - For unilateral injection, use HCPCS 20610;
 - For a bilateral injection, use HCPCS code 20610-50; and
 - For the hyaluronate agent injected, use J7317, J7320 or J3490.
- All of the coverage criteria must be met before this service can be reimbursed by Medicare,
- Diagnosis (es) must be present on any claim submitted, and be coded to the highest level of specificity, and;
- The diagnosis codes(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 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.

Utilization Guidelines

N/A

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.

Financial Responsibility:

Provider Liable

The provider of the service or the ordering physician must have notified the patient in writing, prior to the service, and obtained a signature verifying Advance Beneficiary Notice. Without prior notice, services denied as not medically necessary cannot be billed to the beneficiary. The provider is liable.

Beneficiary Liable

If there is clear evidence that the beneficiary was issued and signed an Advanced Beneficiary Notice (ABN) prior to the service, the liability rests with the beneficiary. Claims for dates of service prior to January 1, 2003 should contain the condition code 20 and occurrence code 32, with date to signify that an ABN was issued to the beneficiary. Absence of these codes will result in a provider liable determination

Claims for dates of service beginning January 1, 2003 should contain the occurrence code 32 with date to signify that an ABN was issued to the beneficiary. Absence of this code will result in a provider liable determination.

Reference: PM AB-02-168, CR 2415

Sources of Information and Basis for Decision

- 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

Advisory Committee Notes

This policy does not reflect the sole opinion of the contractor or Contractor Medical Director. Although the final decision rests with the contractor, this policy was developed in cooperation with advisory groups, which includes representatives from the appropriate specialty (ies).

Advisory Committee Meeting Date:

Start Date of Comment Period

N/A

End Date of Comment Period

N/A

Start Date of Notice Period

N/A

Revision History

<u>Number</u>	<u>Date</u>	<u>Change</u>
99-06-R6	03/09/05	Addition of Orthovisc billed under J3490.
99-06-R5	10/01/2003	CPT/HCPCS code descriptors changed to short descriptors. Spelling errors corrected.
99-06-R4	01/01/2003	Annual update of CPT/HCPCS codes. Addition of J7317, codes Q3030 and J7316 discontinued, effective 01/01/2003 with a 3-month grace period.
99-06-R3	10/01/2002	Addition of Q3030, effective 10/01/2002 and J7316 discontinued on 06/30/2002, with a 90-day grace period, per AB 02-082, CR 2230.
99-06-R2	01/01/2002	Addition of <i>J7316-Sodium Hyaluronate, 5 mg</i> and deletion of J7315-20 mg.
99-06-R1	11/17/2000	Deletion of J3490 and replaced with HCPCS Level II codes J7315 and J7320.

THIS BULLETIN SHOULD BE SHARED WITH ALL HEALTH CARE PRACTITIONERS AND MANAGERIAL MEMBERS OF THE PROVIDER/SUPPLIER STAFF. BULLETINS ISSUED AFTER OCTOBER 1, 1999 ARE AVAILABLE FROM OUR WEBSITE AT www.marylandmedicare.com

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