GUIDELINES
This policy does not certify benefits or authorization of benefits, which is designated by each individual policyholder contract. Paramount applies coding edits to all medical claims through coding logic software to evaluate the accuracy and adherence to accepted national standards. This guideline is solely for explaining correct procedure reporting and does not imply coverage and reimbursement.

DESCRIPTION
Osteoarthritis is the most common form of arthritis. Pathologically in the knee, osteoarthritis is characterized by deterioration and loss of articular cartilage, subchondral sclerosis and osteophyte formation. Since there are no curative therapies for osteoarthritis at this time, the overall goals of existing therapies are to reduce pain, prevent disability, and postpone the need for total knee replacement surgery. Various non-pharmacologic (e.g., weight loss, physical therapy) and pharmacologic (e.g., acetaminophen, non-steroidal anti-inflammatory [NSAIDs], intra-articular injections of corticosteroids, intra-articular hyaluronates) treatment modalities are utilized.

Viscosupplements contain hyaluronate. Hyaluronates are also referred to as hyaluronic acid or hyaluronan. Clinical studies of sodium hyaluronate and hylan G-F-20 have demonstrated that injection of these agents into the joint space of osteoarthritic knees is sometimes marginally more effective than placebo procedures in reduction of pain and improvement in functional capacity in some patients. These marginal beneficial results are more pronounced with the larger molecular weight compound hylan G-F20. There is no data indicating that these agents reverse or retard the osteoarthritic process in the injected joints. The long-term effects of repeated injections are unknown.

POLICY

| HMO, PPO, Individual Marketplace | Effective 5/25/18 viscosupplementation (C9465, J7320-J7328) for all indications including osteoarthritis of the knee is non-covered. |
| Advantage and Elite | Viscosupplementation using Synvisc or Synvisc-One (J7325) for osteoarthritis of the knee does not require prior authorization. |
| Viscosupplementation using other brands (C9465, J7320-J7324, J7326-J7328) is non-covered. |

HMO, PPO, Individual Marketplace
The use of viscosupplementation (C9465, J7320-J7328) is not covered for osteoarthritis of the knee or for any other indications. There is no clinical significant evidence supporting intraarticular hyaluronic acid injection(s) decrease knee arthroplasty.

Advantage, Elite
An initial course of viscosupplementation (J7325) is considered medically necessary for the treatment of pain due to osteoarthritis of the knee when ALL of the following criteria are met:
1. There is documentation of a diagnosis of osteoarthritis and there is no evidence of inflammatory arthritis (for example, rheumatoid arthritis).
2. There is documentation that the pain interferes with functional activities (for example, ambulation, prolonged standing).
3. There is documentation of failure to respond adequately to at least 3 months of conservative therapy which includes activity modification, home exercise, protective weight bearing, and analgesics (for example, acetaminophen or non-steroidal anti-inflammatory drugs [NSAIDs]) or the individual is unable to tolerate conservative therapy because of adverse side effects.
4. There are no contraindications to the injections (for example, active joint infection, bleeding disorder).

A repeat course of viscosupplementation (J7325) is considered medically necessary for the treatment of pain due to osteoarthritis of the knee for individuals who meet ALL of the following criteria:
1. The individual met all of the criteria for an initial course of treatment.
2. Six (6) months, or more, have elapsed since the conclusion of the prior treatment cycle.
3. There is documentation that the prior course of treatment resulted in pain relief and improvement in functional status.

Paramount does not cover viscosupplementation for the treatment of osteoarthritis in locations other than the knee because it is considered experimental, investigational or unproven.

Viscosupplementation (J7325) for osteoarthritis of the knee should be reported with injection procedure code 20610. Procedures J7325 will be denied when reported with procedures 20600, 20604, 20605, 20606, for locations other than the knee (e.g. temporomandibular, acromioclavicular, wrist, elbow, or ankle, olecranon bursa).

Note: Ultrasound guidance, fluoroscopic guidance and knee arthrography for viscosupplement injections is considered experimental and investigational because it has not been established that this approach will improve health outcomes.

Preferred and Medically Necessary Brand of Viscosupplement:
There are several brands of viscosupplement on the market. There is a lack of reliable evidence that any one brand of viscosupplement is superior to other brands for medically necessary indications.

Consequently, because other brands of viscosupplement are at least as likely to produce equivalent therapeutic results, no other brands of viscosupplement (C9465, J7320-J7324, J7326-J7328) will be considered medically necessary unless the member has a documented contraindication or intolerance to Paramount's preferred brand of viscosupplement: Synvisc or Synvisc-One (J7325).

Documentation Requirements:
- All documentation must be maintained in the patient's medical record and made available upon request.
- Every page of the record must be legible and include appropriate patient identification information (e.g., complete name, dates of service(s)). The documentation must include the legible signature of the physician or non-physician practitioner responsible for and providing the care to the patient.
- The submitted medical record must support the use of the selected ICD-10-CM code(s). The submitted CPT/HCPCS code must describe the service performed.
- The medical record documentation must support the medical necessity of the services as directed in this policy.
- 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. The appropriate records documenting the improvement must be maintained in the medical record and made available to Medicare upon request.
- An X-ray report of the knees must be available in the event of a review.
- Medical records should reflect failure of conservative treatment defined as physical therapy and use of simple non-narcotic analgesics including acetaminophen.
- When billing for a drug/biological, any amount of medication wasted must be clearly documented in the medical record. The documentation must include the date, time, amount of medication wasted, and the reason for the wastage.

CODING/BILLING INFORMATION
The appearance of a code in this section does not necessarily indicate coverage. Codes that are covered may have selection criteria that must be met. Payment for supplies may be included in payment for other services rendered.

<table>
<thead>
<tr>
<th>CPT CODE</th>
<th>Description</th>
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<tbody>
<tr>
<td>20610</td>
<td>Arthrocentesis, aspiration and/or injection, major joint or bursa (e.g. shoulder, hip, knee joint, subacromial bursa)</td>
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<table>
<thead>
<tr>
<th>HCPCS CODES</th>
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<tbody>
<tr>
<td>C9465</td>
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<td>J7320</td>
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<table>
<thead>
<tr>
<th>ICD-10 CODES that Support Medical Necessity</th>
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</thead>
<tbody>
<tr>
<td>M17.0</td>
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<td>M17.10</td>
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</table>
M17.11 Unilateral primary osteoarthritis, right knee
M17.12 Unilateral primary osteoarthritis, left knee
M17.2 Bilateral post-traumatic osteoarthritis of knee
M17.30 Unilateral post-traumatic osteoarthritis, unspecified knee
M17.31 Unilateral post-traumatic osteoarthritis, right knee
M17.32 Unilateral post-traumatic osteoarthritis, left knee
M17.4 Other bilateral secondary osteoarthritis of knee
M17.5 Other unilateral secondary osteoarthritis of knee
M17.9 Osteoarthritis of knee, unspecified

REVISION HISTORY EXPLANATION
01/01/10: Added code J7325
01/01/12: Added code J7326
06/22/12: Added new code
11/11/14: J7326 is non-covered for Advantage per OAC rule 5160-4-12. Policy reviewed and updated to reflect most current clinical evidence per Medical Policy Steering Committee.
01/12/16: Removed deleted code J7322. Added effective 1/1/15 new code J7327. Policy reviewed and updated to reflect most current clinical evidence per Medical Policy Steering Committee.
05/19/16: J7326 is covered effective 4/1/16 for Advantage per OAC rule 5160-4-12.
08/09/16: Added new codes C9471, J7328 & Q9980. Paramount's preferred brand of viscosupplement: Synvisc or Synvisc-One (J7325) is now required for all product lines. Policy reviewed and updated to reflect most current clinical evidence per Medical Policy Steering Committee.
03/13/18: Effective 01/01/18 revised codes J7321 & J7328. Removed effective 12/31/16 deleted codes C9471 and Q9980. Added codes J7320 & J7322. Viscosupplementation (J7320-J7328) for all indications including osteoarthritis of the knee is non-covered for HMO, PPO, & Individual Marketplace. Viscosupplementation using Synvisc or Synvisc-One (J7325) for osteoarthritis of the knee will continue to be covered without prior authorization for Advantage and Elite. Viscosupplementation using other brands (J7320-J7324, J7326-J7328) for osteoarthritis of the knee is non-covered for Advantage and Elite. Added ICD-10 diagnosis codes per CMS guidelines. Ultrasound guidance, fluoroscopic guidance and knee arthrography for viscosupplement injections is non-covered. Policy reviewed and updated to reflect most current clinical evidence per Medical Policy Steering Committee.
04/10/18: Added effective date 5/25/18 for Viscosupplementation (J7320-J7328) for all indications including osteoarthritis of the knee is non-covered for HMO, PPO, & Individual Marketplace. Policy reviewed and updated to reflect most current clinical evidence per Medical Policy Steering Committee.
08/14/18: Added new code effective 4/1/18 C9465 as non-covered for all product lines. Policy reviewed and updated to reflect most current clinical evidence per Medical Policy Steering Committee.
04/09/19: Updated documentation verbiage, per ODI review/direction and medical impromptu meeting review (Medical Director, Utilization, Medical Policy Research) clarifying that viscosupplementation is non-covered, as evidenced by no supporting documentation indication for clinical benefit, for the HMO, PPO, Individual Marketplace product lines. Noted; coverage for the Advantage and Elite product lines is per governmental regulations/direction.
04/15/19: Updated documentation verbiage per Director of Regulatory Compliance - The use of viscosupplementation (C9465, J7320-J7328) is not covered for osteoarthritis of the knee or for any other indication.

REFERENCES/RESOURCES
Centers for Medicare and Medicaid Services, CMS Manual System and other CMS publications and services
Ohio Department of Medicaid http://dfs.ohio.gov/
American Medical Association, Current Procedural Terminology (CPT®) and associated publications and services
Centers for Medicare and Medicaid Services, Healthcare Common Procedure Coding System, HCPCS Release and Code Sets
Industry Standard Review
Hayes, Inc.