Intent:

The intent of this policy/guideline is to provide information to the prescribing practitioner outlining the coverage criteria for hyaluronates under the patient's prescription drug benefit.

Description:

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

FDA-Approved Indication
Treatment of pain in osteoarthritis of the knee in patients who have failed to respond adequately to conservative non-pharmacologic therapy and simple analgesics (e.g., acetaminophen)

All other indications are considered experimental/investigational and not medically necessary.

Applicable Drug List:

Gel-One
Visco-3

Note: products other than Gel-One and Visco-3 will not be covered.

Policy/Guideline:

Criteria for Initial Approval:
Osteoarthritis (OA) of the Knee
Authorization of 12 months may be granted for treatment of osteoarthritis (OA) in the knee when all of the following criteria are met:

A. The diagnosis is supported by radiographic evidence of osteoarthritis of the knee (e.g., joint space narrowing, subchondral sclerosis, osteophytes and sub-chondral cysts) or the member has at least 5 of the following signs and symptoms:
   1. Bony enlargement
   2. Bony tenderness
   3. Crepitus (noisy, grating sound) on active motion
   4. Erythrocyte sedimentation rate (ESR) less than 40 mm/hr
   5. Less than 30 minutes of morning stiffness
   6. No palpable warmth of synovium

7. Over 50 years of age
8. Rheumatoid factor less than 1:40 titer (agglutination method)
9. Synovial fluid signs (clear fluid of normal viscosity and WBC less than 2000/mm^3)

B. The member has knee pain which interferes with functional activities (e.g., ambulation, prolonged standing).
C. The member has experienced an inadequate response or adverse effects with non-pharmacologic treatment options (e.g., physical therapy, regular exercise, insoles, knee bracing, weight reduction).
D. The member has experienced an inadequate response or intolerance or has a contraindication to a trial of an analgesic (e.g., acetaminophen up to 3 to 4 grams per day, non-steroidal anti-inflammatory drugs [NSAIDs], topical capsaicin cream) for at least 3 months.
E. The member has experienced an inadequate response or intolerance or has a contraindication to a trial of intraarticular steroid injections for at least 3 months.
F. The member is not scheduled to undergo a total knee replacement within 6 months of starting treatment.

Continuation of Therapy:
Authorization of 12 months may be granted for continued treatment of osteoarthritis in the knee when all of the following criteria are met:
A. Member meets all criteria for initial approval.
B. Member has experienced improvement in pain and functional capacity following the previous injections.
C. At least 6 months has elapsed since the last injection in the prior completed series of injections.

Approval Duration and Quantity Restrictions:
Approval: 12 months

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