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 Indications[1-17]

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:

Coverage Criteria

Osteoarthritis (OA) of the Knee[1-24]

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

- 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:
  - Bony enlargement
  - Bony tenderness
  - Crepitus (noisy, grating sound) on active motion
  - Erythrocyte sedimentation rate (ESR) less than 40 mm/hr
  - Less than 30 minutes of morning stiffness

  - No palpable warmth of synovium
  - Over 50 years of age
  - Rheumatoid factor less than 1:40 titer (agglutination method)
  - Synovial fluid signs (clear fluid of normal viscosity and WBC less than 2000/mm^3)
- The member has knee pain which interferes with functional activities (e.g., ambulation, prolonged standing).
- 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).
- 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.
- 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.
- 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:

- Member meets all requirements in the coverage criteria.
- Member has experienced improvement in pain and functional capacity following the previous injections.
- 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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