AETNA BETTER HEALTH®
Non-Formulary Prior Authorization guideline for Hyaluronic Acid Derivatives

Hyaluronic Acid Derivatives

- **Injection:** Preferred Agents – Gel-One and Hyalgan
  - Non-preferred injectable agents require documentation of contraindication to preferred products.

- **Topical:**
  - Bionect
  - HyGel
  - Hylira
  - XClair

Authorization guidelines
For patients who have the following:

1. **Treatment of osteoarthritis of the knee, for members at least 18 years of age**
   a. Documentation to support which knee is to be treated (right, left, or bilateral)
   b. Trial and failure or contraindications to conservative non-pharmacologic therapy (i.e., physical therapy, land based or aquatic based exercise, resistance training, or weight loss)
   c. Adequate trial and failure or contraindications pharmacologic therapy to one of the following (i.e. acetaminophen, NSAID’s, otc capsaicin, or tramadol)
   d. Trial and failure or intolerance to steroid injections
   e. Radiographic evidence of mild to moderate osteoarthritis of the knee (e.g., severe joint space narrowing, subchondral sclerosis, osteophytes) OR if unavailable,
   f. Documented symptomatic osteoarthritis of the knee according to American College of Rheumatology (ACR) clinical and laboratory criteria, which requires knee pain and at least 5 of the following:
      i. Bony enlargement
      ii. Bony tenderness
      iii. Crepitus (noisy, grating sound) on active motion
      iv. Erythrocyte sedimentation rate (ESR) less than 40 mm/hr
      v. Less than 30 minutes of morning stiffness
      vi. No palpable warmth of synovium
      vii. Over 50 years of age
      viii. Rheumatoid factor less than 1:40 titer (agglutination method)
      ix. Synovial fluid signs (clear fluid of normal viscosity and WBC less than 2000/mm3);
   g. The member reports pain which interferes with functional activities (e.g., ambulation, prolonged standing)
2. Treatment of burns, dermal ulcers, wounds, radiation dermatitis for members at least 18 years of age
   a. Prescriber must be a dermatologist
3. Treatment of xerosis for members at least 18 years of age
   a. Prescriber must be a dermatologist
   b. Trial and failure of ammonium lactate or a topical corticosteroid

Authorization and Limitations

Initial Approval Duration:
- 6 months per treatment course
- Burns or dermatitis: 3 fills of generic agent
- Xerosis: up to 1,000 grams of equivalent generic agent per 30 days for three months

Renewal:
- 6 months has elapsed since initial treatment
- Documentation to support improved response to treatment and a dose reduction with NSAIDs or other analgesics

Non Coverage Criteria:
- Use not approved by the FDA; AND
- The use is unapproved and not supported by the literature or evidence as an accepted off-label use.
- Diagnosis of Osteoarthritis of the hip, hand, shoulder, etc
- Indications for the following (not all inclusive):
  - Temporomandibular joint disorders
  - Chondromalacia of patella [chondromalacia patellae],
  - Pain in joint, lower leg [patellofemoral syndrome],
  - Osteoarthritis and allied disorders [joints other than knee]
- Any Hypersensitivity to hyaluronics, i.e, active joint infection or bleeding. Some products are produced from avian sources; use with caution in patients with hypersensitivity to avian proteins, feathers, or egg products. Use Gel-One with caution in patients allergic to cinnamon
- Treatment within 6 months of knee surgery
- No more than 2 series of injections allowed per knee per lifetime

Medically Necessary — A service or benefit is Medically Necessary if it is compensable under the MA Program and if it meets any one of the following standards:

- The service or benefit will, or is reasonably expected to, prevent the onset of an illness, condition or disability.
- The service or benefit will, or is reasonably expected to, reduce or ameliorate the physical, mental or developmental effects of an illness, condition, injury or disability.
- The service or benefit will assist the Member to achieve or maintain maximum functional capacity in performing daily activities, taking into account both the functional
capacity of the Member and those functional capacities that are appropriate for Members of the same age.

Determination of Medical Necessity for covered care and services, whether made on a Prior Authorization, Concurrent Review, Retrospective Review, or exception basis, must be documented in writing.

The determination is based on medical information provided by the Member, the Member’s family/caretaker and the Primary Care Practitioner, as well as any other Providers, programs, agencies that have evaluated the Member.

All such determinations must be made by qualified and trained Health Care Providers. A Health Care Provider who makes such determinations of Medical Necessity is not considered to be providing a health care service under this Agreement.

References: