MDWISE PRIOR AUTHORIZATION CRITERIA FOR HYALURONIC ACID DERIVATIVES

EUFLEXXA® (hyaluronate sodium): 20 mg/2ml syringe
HYALGAN® (hyaluronate sodium): 20 mg/2ml syringe
SYNVISC® (hylan G-F 20): 16 mg/2ml syringe
SUPARTZ® (hyaluronate sodium): 25 mg/2.5 ml syringe
ORTHOVISC® (hyaluronate sodium): 30 mg/2 ml syringe

NEWLY MARKETED hyaluronic acid derivative

PREFERRED PRODUCT: Euflexxa®

PA CRITERIA FOR INITIAL APPROVAL:

- There is documentation of mild to moderate Osteoarthritis (OA)/Degenerative joint disease (DJD) (grade 1-3) of the knee
  - Grade 1: slight narrowing of the joint, minimum osteophyte formation, and slight sclerosis
  - Grade 2: moderate joint space narrowing, spur formation, and sclerosis
  - Grade 3: bone-on-bone changes and sclerosis but no loss of bone stock
  - Grade 4: complete obliteration of the joint, loss of joint stock and severe sclerosis (Hyaluronic acid derivatives are not recommended therapy in patients with grade 4 or severe DJD)
- There is documentation that the patient recently (over the past 4 months) has had adequate trials on simple analgesics (acetaminophen containing products or topical capsaicin cream) & NSAIDS (including 2 different prescription strength NSAIDS) on a continuous basis for 3 months without success or has a medical reason (intolerance, hypersensitivity, contraindication, etc) for not being able to utilize simple analgesic products and NSAIDS
- The patient has recently (within past 2 months) tried steroid injections and aspiration for effusion without success, per affected knee or has a medical reason for not being able to utilize steroid injections
- If the medication request is for Hyalgan, Synvisc, Supartz, Orthovisc or any other newly marketed hyaluronic acid derivative (HAD), the patient has a documented medical reason (intolerance, hypersensitivity, contraindication, etc) for not taking Euflexxa® to treat their medical condition.

If all of the above conditions are met, the request will be approved for a 3 to 5-week duration (based the FDA labeled dose of the HAD requested); if all of the above criteria are not met, the request is referred to a Medical Director for medical necessity review.

PA CRITERIA FOR RE-AUTHORIZATION:

- At least 6 months have elapsed since the previous course of HAD therapy for the treated knee(s).
- Documentation was submitted that the patient had an objective response to the treated knee(s) that lasted for ≥ 6 months to previous HAD therapy, as documented by at least ONE of the following:
  - Decreased joint pain and/or stiffness as measured by a visual analog scale (VAS)
  - Improvement in standard indices such as WOMAC osteoarthritis index or Lequesne’s functional index (See Glossary for definitions)
  - Improved knee range of motion by goniometer
  - Decrease in midpatellar knee circumference in millimeters
  - Synovial effusion absent or volume decreased
  - Decrease in the need for intra-articular agents (anesthetics, corticosteroids), knee aspiration, analgesics or anti-inflammatory medications for the management of the treated knee(s) following the previous course of HAD that is consistent with pharmacy claims data.
- Documentation was submitted that the patient has a return of symptoms of osteoarthritis.
- There is documentation that the patient recently had an adequate re-trial on simple analgesics (acetaminophen containing products or topical capsaicin cream) & NSAIDS (including 2 different prescription strength NSAIDS) on a continuous basis for 3 months without success or has a medical reason (intolerance, hypersensitivity, contraindication, etc) for not being able to utilize simple analgesic products and NSAIDS
- The patient has recently (within past 2 months) tried steroid injections and aspiration for effusion without success, per affected knee or has a medical reason for not being able to utilize steroid injections
- Documentation submitted indicates that the patient does not have grade 4 OA or severe DJD

If all of the above conditions are met, the request will be approved for a 3 to 5-week duration (based the FDA labeled dose of the HAD requested); if all of the above criteria are not met, the request is referred to a Medical Director for medical necessity review.

FDA INDICATION:

Euflexxa®, Hyalgan®, Synvisc®, Supartz® and Orthovisc® are all indicated for the treatment of pain in osteoarthritis (OA) of the knee in patients who have failed to respond to conservative non-pharmacologic therapy and simple analgesics.
REFERENCES:
questions grouped into 3 subscales (pain or discomfort, activities of daily living and maximum distance
Lequesne Functional Severity Index for the knee:
use in research and OA clinical trials.
releva
grouped into 3 subscales (pain, stiffness, and physical function). It measures clinically important patient
administered questionnaire developed to study patients with hip or knee OA. It consists of 24 questions,
Western Ontario and McMaster Universities Osteoarthritis index
Glossary:
subcutaneously prior to administration can be performed.**
Orthovisc:
Supartz::
Synvisc:
Hyalgan:
Euflexxa:
DOSAGE AND ADMINISTRATION:
Rapp S
Brett AS. Journal Watch. Intra
Schwenk TL. Journal Watch. Hyaluronic acid is minimally effective in osteoarthritis. 1/23/04.
Aetna Coverage Policy Bulletins
Medical Policy Synvisc, Supartz, Hyalgan: Blue Cross California
American Journal of
Rheumatology.2004;31:
the effectiveness and
Kirchner M. Marshall K. A double
European journal of
Scali JJ. Intra
Medical Policy Synvisc, Supartz, Hyalgan: Blue Cross California
Aetna Coverage Policy Bulletins. Subject Sodium hyaluronate and Hylan G-F20.4/26/02
Schwenk TL. Journal Watch. Hyaluronic acid is minimally effective in osteoarthritis. 1/23/04.
Brett AS. Journal Watch. Intra-articular hyaluronic acid vs. steroids for knee osteoarthritis. 7/29/03.
24. Euflexxa® product information. 2/06.
26. Orthovisc® product information 6/05.
27. Synvisc® product information 03/10.

Revision/Review Date: MAC 10/12/2011
Associated Policy: Prior Authorization of Medications 236.200

**NOTE:** Clinical reviewer must override criteria when, in his/her professional judgment, the requested item is medically necessary.