

## Criteria for Use of Hylan G-F 20 (Synvisc®) and Sodium Hyaluronate (Hyalgan®)

### I. Indications for VA Patients

Synvisc® and Hyalgan®, regulated in the U.S. as devices rather than drugs, are indicated for the treatment of pain in osteoarthritis (OA) of the knee in patients who meet the following criteria<sup>†</sup>:

- A. Osteoarthritis of the knee(s) (American College of Rheumatology criteria) confirmed by history, exam, x-ray, and synovial fluid analysis.
- B. Documented inadequate control of pain or intolerance to an adequate trial of acetaminophen (4 Grams/day), NSAIDs, intraarticular corticosteroid injections, and other non-narcotic or narcotic analgesics.
- C. Inadequate response to bracing and use of canes or crutches.
- D. Inadequate response to measures such as weight loss and physical therapy.
- E. Surgery is not an option due to concurrent medical conditions that preclude the patient as candidate for surgery. These agents may also be considered as a bridging option before resorting to surgery.

<sup>†</sup> It is strongly recommended that the use of these agents be restricted to specialists in rheumatology and orthopedics.

### II. Dosage and Administration

- A. One treatment cycle of Synvisc® consists of three weekly intra-articular injections administered by a health care provider following strict aseptic technique. Each injection syringe contains 16mg of Hylan G-F20. The treatment cycle of Hyalgan® consists of five weekly intra-articular injections, each containing 20mg of sodium hyaluronate.
- B. Subcutaneous lidocaine or another local anesthetic should be injected prior to administration of Synvisc® and Hyalgan®.
- C. Removal of synovial fluid or effusion, if present, should precede Synvisc® or Hyalgan® therapy.

### III. Warnings/Adverse Events

- A. The use of Synvisc® and Hyalgan® is contraindicated in patients with known hypersensitivity to hyaluronate preparations.
- B. Synvisc® and Hyalgan® should not be injected into knees of patients having skin or knee joint infections or skin diseases at the injection site area.
- C. Transient pain and/or swelling of the injected joint have been reported after intra-articular injection of Synvisc® and Hyalgan®.
- D. The safety of Synvisc® and Hyalgan® has not been studied in pregnant women, and thus, should be avoided during pregnancy.

### IV. Monitoring Parameters

- A. Patients with allergies to avian proteins, feathers, and egg products should be monitored for allergic reactions, since Synvisc® and Hyalgan® are extracted from combs of roosters.
- B. Drug Interactions
  1. Concurrent administration of other medications into the knee during Synvisc® or Hyalgan® therapy may compromise the safety and effectiveness of the agents and is, therefore, discouraged.
  2. Disinfectants containing quaternary ammonium salts should not be used for skin preparation as hyaluronic acid can precipitate under such conditions.

### V. Outcomes

Studies have shown Synvisc® and Hyalgan® to reduce pain and functional impairment associated with OA of the knee. One treatment cycle may provide up to six months of pain relief; however, the safety and effectiveness of repeat treatment cycles has not been well established.

### VI. Cost Information

The cost of drug for one treatment cycle of Synvisc® (3 weekly injections) into ONE knee is \$493.28, and that of Hyalgan® (5 weekly injections) is \$448.50. (Clinic cost for drug administration not included).

#### Nonsteroidal Anti-Inflammatory

##### Drugs (per month)

Ibuprofen 800mg tid \$1.87  
Naproxen 500mg bid \$4.23  
Diclofenac 75mg bid \$6.75  
Sulindac 200mg bid \$2.39  
Salsalate 1500mg bid \$2.83  
Etodolac 300-400mg bid \$0.01-10.80

Nabumetone 750mg bid \$45.75  
Celecoxib 100-200mg qd \$53.25-90.12  
Rofecoxib 12.5 or 25mg qd \$45.00  
Tolmetin 400mg tid \$13.50  
Indomethacin 25mg tid \$2.70  
Piroxicam 20mg qd \$1.20

#### Glucocorticoids (per injection)

Triamcinolone acetonide inj. 40mg \$3.18  
Methylprednisolone acetate inj. 40mg \$1.34  
Prednisone 10-40mg QD \$1.50-\$6.17 per mth  
Analgesics (per month)  
Acetaminophen 1gm QID \$6.00  
APAP 650mg/propox. 100mg QID \$15.96  
Tramadol 50mg tid \$34.84