Hyaluronic Acid Derivatives:

Durolane®, Euflexxa™, Gel-One®, GelSyn-3™, GenVisc 850®, Hyalgan™, Hymovis®, Hymovis® One, Monovisc®, Orthovisc™, Supartz FX™, Synojoynt, Synvisc™, & Synvisc-One™, Triluron™, TriVisc™, VISCO-3

Some agents on this policy may require step therapy *See* "Step Therapy Requirements for Provider Administered Specialty Medications" Document at:
https://www.bcbst.com/docs/providers/Comm_BC_PAD_Step_Therapy_Guide.pdf

IMPORTANT REMINDER

We develop Medical Policies to provide guidance to Members and Providers. This Medical Policy relates only to the services or supplies described in it. The existence of a Medical Policy is not an authorization, certification, explanation of benefits or a contract for the service (or supply) that is referenced in the Medical Policy. For a determination of the benefits that a Member is entitled to receive under his or her health plan, the Member's health plan must be reviewed. If there is a conflict between the medical policy and a health plan or government program (e.g., TennCare), the express terms of the health plan or government program will govern.

POLICY

INDICATIONS

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
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.

COVERAGE CRITERIA

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:

- 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.

APPLICABLE TENNESSEE STATE MANDATE REQUIREMENTS

BlueCross BlueShield of Tennessee's Medical Policy complies with Tennessee Code Annotated Section 56-7-2352 regarding coverage of off-label indications of Food and Drug Administration (FDA) approved drugs when the off-label use is recognized in one of the statutorily recognized standard reference compendia or in the published peer-reviewed medical literature.

ADDITIONAL INFORMATION

For appropriate chemotherapy regimens, dosage information, contraindications, precautions, warnings, and monitoring information, please refer to one of the standard reference compendia (e.g., the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) published by the National Comprehensive Cancer Network®, Drugdex Evaluations of Micromedex Solutions at Truven Health, or The American Hospital Formulary Service Drug Information).

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EFFECTIVE DATE 4/30/2026

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