

POLICY & PRACTICE

New RA Quality Measures Drafted

The National Committee for Quality Assurance, the American Medical Association, and Mathematica Policy Research Inc. have released a draft set of 22 clinical measures that assess physician performance in rheumatoid arthritis; palliative and end-of-life care; endoscopy and polyp surveillance; and chronic wound care. When made final, the measures will be submitted to the Centers for Medicare and Medicaid Services for possible inclusion in its pay-for-reporting program, according to NCQA. The measures also could be used

in other quality improvement initiatives, in maintenance of certification programs, or as part of pay-for-performance programs. The development of the measures will help CMS officials and others "drive quality improvement," Margaret E. O'Kane, NCQA president, said in a statement. The draft set six measures related to rheumatoid arthritis, which were developed in collaboration with the American College of Rheumatology.

Feds Seek Help in Bone Campaign

The federal government is reaching out to

organizations that promote bone health and girls' health to help to increase national awareness of behaviors that contribute to good bone health in girls. The Department of Health and Human Services' Office of Women's Health recently issued a request for groups to offer advice on the development and dissemination of campaign materials related to the National Bone Health Campaign. The campaign is aimed at helping girls increase their calcium and vitamin D consumption and weight-bearing physical activity with the goal of building strong bones. The national social marketing campaign will target girls, parents, and health care providers.

Vioxx Victories

Merck & Co. cannot be sued for the cost of medical monitoring associated with past use of Vioxx (rofecoxib), according to a recent ruling from the New Jersey Supreme Court. That court overruled an appellate court and found that individuals who used Vioxx, but had not suffered an injury related to the drug, could not sue the company for the cost of monitoring, such as electrocardiograms or follow-up cardiology consultations. Merck also scored a victory in Texas when a state appeals court overturned a 2005 jury verdict against the company. In that case, *Ernst v. Merck*, the jury had originally awarded the plaintiff more than \$24 million in compensatory damages and \$229 million in punitive damages. The punitive damages award had already been reduced to \$1.65 million under a Texas law that limits punitive damages.

AHIP Proposes Reform Plan

The United States could reduce total health care spending by \$145 billion in the next 7 years while improving the quality of patient care by implementing five proposals, according to a plan from the industry group America's Health Insurance Plans. The AHIP plan endorsed a combination of measures to improve the U.S. health care system and save money, including prevention; better disease management and care coordination; a move to electronic transactions; a transition to a value-based payment system; and new technology. The group also called for replacing the current medical liability system with dispute resolution that would put in place an objective, independent administrative process to provide a quick and fair end to disputes and promote evidence-based medicine. AHIP President and CEO Karen Ignagni said that most pieces of her group's proposal now are in use by health insurance companies. "Plans have made measurable progress, but the nation needs a coordinated approach across the public and private sectors to maximize the impact of these strategies," she said in a statement.

CMS Outlines Hospice Rights

CMS has made final regulations that give Medicare beneficiaries with terminal illnesses the right to determine how they receive end-of-life care. The provisions, contained in an overhaul of regulations governing the hospice industry, include explicit language on patient rights that had not existed under the previous regulations, CMS said. According to the new rule, patients who choose hospice or palliative care over curative treatment are entitled to such things as participation in their treatment plan, the right to effective pain management, the right to refuse treatment, and the right to choose their own physician. CMS noted that although many hospice patients already are active in their own treatment plans, this regulation is the first to set out a detailed list of patient rights. "End-of-life care has changed markedly in the past 25 years and it is time to update our regulations to reflect advances in medicine and hospice industry practices as well as patient rights," said CMS Acting Administrator Kerry Weems in a statement.

—Mary Ellen Schneider



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HCPCS CODE
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BRIEF SUMMARY

Please consult package insert for full Prescribing Information.

INDICATION

EUFLEXXA® (1% sodium hyaluronate) is indicated for the treatment of pain in osteoarthritis (OA) of the knee in patients who have failed to respond adequately to conservative non-pharmacologic therapy and simple analgesics (e.g., acetaminophen).

CONTRAINDICATIONS

- Do not use EUFLEXXA® to treat patients who have a known hypersensitivity to hyaluronan preparations
- Do not use EUFLEXXA® to treat patients with knee joint infections, infections or skin disease in the area of the injection site

WARNINGS

- Mixing of quaternary ammonium salts such as benzalkonium chloride with hyaluronan solutions results in formation of a precipitate. EUFLEXXA® should not be administered through a needle previously used with medical solutions containing benzalkonium chloride. Do not use disinfectants for skin preparation that contain quaternary ammonium salts
- Do not inject intravascularly because intravascular injection may cause systemic adverse events

PRECAUTIONS

General

- Patients having repeated exposure to EUFLEXXA® have the potential for an immune response; however, this has not been assessed in humans
- Safety and effectiveness of injection in conjunction with other intra-articular injectables, or into joints other than the knee has not been studied
- Remove any joint effusion before injecting
- Transient pain or swelling of the injected joint may occur after intra-articular injection with EUFLEXXA®
- Do not use after expiration date
- Protect from light
- Do not re-use—dispose of the syringe after use
- Do not use if the blister package is opened or damaged

Information for Patients

- Transient pain and/or swelling of the injected joint may occur after intra-articular injection of EUFLEXXA®
- As with any invasive joint procedure, it is recommended that the patient avoid any strenuous activities or prolonged (i.e., more than 1 hour) weight-bearing activities such as jogging or tennis within 48 hours following intra-articular injection
- The safety and effectiveness of repeated treatment cycles of EUFLEXXA® have not been established

ADVERSE EVENTS

Adverse event information regarding the use of EUFLEXXA® as a treatment for pain in OA of the knee was available from two sources; a multicenter clinical trial conducted in Germany and a single center clinical trial that was conducted in Israel.

Multicenter Clinical Investigation

This clinical investigation was a prospective randomized, double blinded, active control (commercially available hyaluronan product) study conducted at 10 centers. Three hundred twenty-one patients were randomized into groups of equal size to receive either EUFLEXXA® (n=160) or the active control (n=161). A total of 119 patients reported 196 adverse events; this number represents 54 (33.8%) of the EUFLEXXA® group and 65 (44.4%) of the active control group. There were no deaths reported during the study.

Incidences of each event were similar for both groups, except for knee joint effusion, which was reported by 9 patients in the active control group and one patient in the EUFLEXXA® treatment group. A total of 160 patients received 478 injections of EUFLEXXA®. There were 27 reported adverse

events considered to be related to EUFLEXXA® injections: arthralgia – 11 (6.9%); back pain – 1 (0.63%); blood pressure increase – 3 (1.88%); joint effusion – 1 (0.63%); joint swelling – 3 (1.88%); nausea – 1 (0.63%); paresthesia – 2 (1.25%); feeling of sickness of injection – 3 (1.88%); skin irritation – 1 (0.63%); tenderness in study knee – 1 (0.63%). Four adverse events were reported for the EUFLEXXA® group that the relationship to treatment was considered to be unknown: fatigue – 3 (1.88%); nausea – 1 (0.63%).

Single Center Study

In a single-center, single-blinded, placebo controlled, prospective, two parallel treatment arm clinical trial a total of 49 (25 EUFLEXXA®, 24 placebo) patients were randomized into two treatment groups in a ratio of 1:1 EUFLEXXA® or placebo. A total of 65 adverse events were reported by 17 (68%) of the patients in the EUFLEXXA® group and 15 (63%) in the placebo group. Of the 65 total events reported, 20 were regarded as treatment related. Knee pain, hypokinesia of the knee, knee swelling, and rash were considered to be treatment related adverse events.

DETAILED DEVICE DESCRIPTION

Each syringe of EUFLEXXA® contains:

Sodium hyaluronate	20 mg
Sodium chloride	17 mg
Disodium hydrogen phosphate dodecahydrate	1.12 mg
Sodium dihydrogen phosphate dihydrate	0.1 mg
Water for injection	q.s.

HOW SUPPLIED

EUFLEXXA® is supplied in 2.25 ml nominal volume, disposable, pre-filled glass syringes containing 2 ml of EUFLEXXA®. Only the contents of the syringe are sterile. EUFLEXXA® is nonpyrogenic. 3 disposable syringes per carton.

This product is latex-free.

DIRECTIONS FOR USE

- Do not use EUFLEXXA® if the package is open or damaged. Store in the original package below 77°F (25°C). Do not freeze. Protect from light.
- EUFLEXXA® is administered by intra-articular injection into the knee synovial capsule using strict aseptic injection procedures. The full content of the syringe is injected into the affected knee at weekly intervals for 3 weeks, for a total of 3 injections.

Toll free number for providers and patients to call with questions: 1-(888)-FERRING (1-(888)-337-7464).

MANUFACTURED FOR:

FERRING
PHARMACEUTICALS

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References: 1. IMS data. February 2008. 2. Kirchner M, Marshall D. A double-blind randomized controlled trial comparing alternate forms of high molecular weight hyaluronan for the treatment of osteoarthritis of the knee. *Osteoarthritis Cartilage*. 2006;14:154-162.