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June 2017

Drug of the Month

Kevzara® (sarilumab)

The biologic product Kevzara® (sarilumab) received Food and Drug Administration (FDA) approval on May 22, 2017, for the treatment of adult patients with moderately to severely active rheumatoid arthritis who have had an inadequate response or intolerance to one or more disease-modifying antirheumatic drugs (DMARDs). In general, biologics are similar to chemical drugs but typically represent larger, more complex molecules that are derived from living cells or organisms. These properties contribute to added concerns for administration, storage, manufacturing, and immunogenicity.

Kevzara is an injectable product available as 150 mg/1.14 mL or 200 mg/1.14 mL solution in a single-dose, pre-filled syringe for subcutaneous use. The recommended dosing is 200 mg to be injected once every two weeks, and Kevzara may be used alone or in combination with methotrexate or other (non-biologic) DMARDs. A reduced dose of 150 mg once every two weeks is recommended with neutropenia, thrombocytopenia, or elevated liver enzymes (ALT). Kevzara works by blocking interleukin-6 (IL-6) signaling within the body, which affects inflammatory response.

Patients should be monitored for the occurrence of opportunistic infections during therapy as they may be at an increased risk of hospitalization or death from serious infections such as tuberculosis (TB), bacterial sepsis, and invasive fungal infections (e.g., histoplasmosis). Due to these risks, it is recommended that the patient undergo a test for latent TB before starting Kevzara, and the patient should continue to be evaluated for active TB periodically throughout Kevzara treatment. Patients with any active infection should not be started on Kevzara, and live vaccines or therapeutic infectious agents should not be given with Kevzara. The most common adverse effects reported with Kevzara use include neutropenia, elevated liver enzymes, injection site redness of the skin, upper respiratory tract infections, and urinary tract infections.

Biologic medications like Kevzara fall in the "specialty" drug category, and additional oversight is recommended due to the complex or costly nature of these types of drugs. Furthermore, the condition treated by Kevzara is not typically considered to be work-related as a person is genetically predisposed to have this diagnosis. The appropriateness for use of Kevzara in relation to the work injury should be determined prior to coverage consideration.

Reference: www.accessdata.fda.gov/scripts/cder/daf/

Formulary Updates

- State of Arkansas has a formulary effective date of September 1, 2017 with written public comment submissions completed by June 14, 2017.
- State of California has revisions occurring, plans to have another 15-day public comment period, and anticipates an implementation date of January 1, 2018.
- State of Louisiana HB 529 (06/01/2018) no action since April 10, 2017. HB 592 (01/01/2018) referred to the Committee on Labor and Industrial Relations May 30, 2017, with no other action reported at this time.
- State of New York will establish a formulary on or before December 31, 2017.

Why would someone be prescribed a steroid for pain?

Corticosteroids are often prescribed to assist with acute or short-term pain as they are powerful anti-inflammatories. The body's natural pain response involves a flooding of the site of injury with various mediators for healing and repair. This response leads to an increase in blood flow and fluid to the area which, in turn, leads to swelling, redness, heat, and pain. Naturally-occurring corticosteroids are produced in the body by the "cortex" or outer portion of the adrenal gland, which is where this class of drugs gets its name. In general, the type of corticosteroids referred to as "glucocorticoids" can act to stem the swelling or inflammation that goes along with most injuries. Some examples of common glucocorticoid corticosteroids include cortisone, hydrocortisone (Cortef®), prednisone, prednisolone (Orapred®), methylprednisolone (Medrol®, Depo-Medrol®, Solu-Medrol®), triamcinolone (Kenalog®, Aristospan®), dexamethasone, and betamethasone (Celestone®). Corticosteroids are distinguished from non-steroidal anti-inflammatory drugs (NSAIDs) as each class has unique characteristics, mechanisms of action, and anticipated adverse effects. Adverse effects indicative of the corticosteroid therapeutic class can vary depending on drug formulation or method of administration (i.e., oral vs. injectable vs. topical) as well as dose and duration of therapy.

Oral Administration

When an oral (i.e., taken by mouth) corticosteroid is prescribed for acute pain or inflammation, the course of therapy is typically administered over a few short days with a higher dose on day one and diminishing doses on subsequent days. Common medications used in this way include Medrol® Dosepak (methylprednisolone 4 mg oral tablets), for example, which is given as a short course of therapy (21 tablets taken over six days) where 6 tablets (24 mg) are taken in four divided doses throughout day one, 5 tablets (20 mg) are taken in divided doses on day two, and so on, with the lowest dose occurring on the final day with 1 tablet (4 mg) used on day six. Oral dosing is generally done in this way to get the most "bang for the buck," so-to-speak. The dosing schedule helps to achieve the most effective anti-inflammatory response while minimizing the risk of side effects with a limited duration of therapy. Corticosteroids are processed through the liver, therefore, use with other drugs that are metabolized by the liver or that affect liver enzymes that play a role in drug metabolism may alter the levels and effectiveness of the corticosteroid.

Injectable Administration

Corticosteroids are also commonly used in injectable form for injury. Injections administered directly into the site of pain such as the lower back (aka, epidural steroid injection [ESI]) or hip joint can allow for some relief. However, reliable evidence of long-term efficacy related to systemic therapy (oral or injectable) with corticosteroids for the indications of pain or injury is generally lacking or variable. According to the Official Disability Guidelines (ODG), "[t]he purpose of ESI is to reduce pain and inflammation, thereby facilitating progress in more active treatment programs, the reduction of medication use and the avoidance of surgery, but this treatment alone offers no significant long-term functional benefit." Many of these injections are performed with a transforaminal technique, which allows for injection of the medication into a more specific target tissue or site and often is done under fluoroscopic guidance with the use of contrast media to ensure needle placement is accurate. Prior to the advent of fluoroscopic guidance, ESIs were typically administered as a "series of three"; however, studies now show that a series of injections is no longer supported by evidence-based research. Essentially when fluoroscopic guidance is used, there is little evidence to support a second epidural steroid injection if the first is ineffective. Epidural steroid injections may also be used as a diagnostic tool in select circumstances. ESIs may be helpful in determining the level or source of pain when symptoms differ from what was seen on diagnostic imaging (such as an MRI) or when imaging is ambiguous, for example. These diagnostic ESI transforaminal injections are also referred to as "selective nerve root blocks," and a patient's response to the local anesthetic may be useful especially in cases where nerve involvement is suspected.

Adverse Effects

The adverse affects associated with corticosteroids are myriad and can range from mild to serious. Furthermore, the incidence of many of these effects can be more evident with higher doses of corticosteroids or use for extended periods of time. Side effects may include salt and fluid retention which can lead to weight gain, swelling of the legs, increases in blood pressure, puffiness of the face, and an increased excretion or loss of potassium. Some of the other side effects may include headache, muscle weakness, loss of blood glucose control, gastrointestinal ulcers, easy bruising of the skin, slow wound healing, glaucoma, cataracts, facial hair growth, menstrual irregularity, and a rounding of the upper back or "buffalo hump," among other effects. Corticosteroids suppress the immune system so considerations for monitoring and managing infection are paramount as well as deferral of routine administration of vaccines until corticosteroid therapy is discontinued. Effects more often associated with prolonged use of corticosteroids may include osteoporosis with or without bone fracture; psychiatric disturbances such as mood swings, insomnia, depression, and personality changes; obesity; increased rate of infection or altered response to vaccines or antibiotics; and effects on the adrenal gland and the body's ability to produce the naturally-occurring corticosteroid, cortisol. This list is by no means exhaustive, and new research continues to be made available related to the effects associated with short- and long-term corticosteroid use.

As a general rule of thumb, if corticosteroids are used they should be administered at the lowest effective dose for the condition being treated and for the shortest possible duration. Decisions to use corticosteroids should involve a risk/benefit discussion between the injured worker and the prescriber to determine appropriateness as well as dose and duration of treatment and whether daily or intermittent therapy should be utilized. Evidence-based treatment guidelines should be considered and followed where available for best outcomes.