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Patient Advocacy

California: Major Win for Patients as Governor Signs Exchange Formulary Transparency Law

A ground breaking new California law gives patients

October 2014

The NAF would like to inform you about an important awareness and treatment opportunity for neuropathy through the Food and Drug Administration (FDA). On April 11, 2013, the FDA published a Federal Register notice (78 FR 21613) and announced the disease areas for meetings in Fiscal Years (FY) 2013-2015. When selecting the set of disease areas, the FDA considers public comments as well as perspectives of review divisions at FDA. While neuropathy was on the FDA's preliminary list of nominated disease states, it unfortunately did not make the final list for meetings in 2013-2015.

The FDA is now commencing a second public process to determine the disease areas for FYs 2016-2017. The FDA will again consider the comments received through the public docket and publish the set of disease areas for 2016-2017 in a Federal Register notice. Neuropathy is NOT included in the preliminary list of nominated disease areas for consideration in the patient-focused drug development meetings; however, neurological and autoimmune diseases treated with IVIG (which includes Multifocal Motor

the ability to view and compare formularies of health plans in both the Exchange and the commercial marketplace. Signed by Governor Jerry Brown (D-CA) on September 25th, the law will provide patients with the information they need to choose a health plan that covers their medicine.

Health plans will be required to allow non-enrollees access to plan formularies and the Exchange will be required to provide links to its plan formularies. The law also directs the state to work with stakeholders to develop a template all health plans must use for presenting formularies. The template must provide information on utilization controls (step therapy, prior authorization) and out of pocket costs for each medicine and also provide patients with information on their rights to access medically necessary medicine.

Pennsylvania Study Committee Recommends Out of Pocket Legislation

The Pennsylvania Legislative Budget and Finance Committee, as a result of study legislation passed in 2013, issued a report in October on Prescription Drug Specialty Tiers in Pennsylvania and their impact on access and patient care. In the report, the committee found that more than 40 percent of patients surveyed delayed filling prescriptions, skipping pills, injections or dosages, and 30 percent stopped taking a drug because it was too expensive. Given these and other findings that detail the high cost-sharing patients face for specialty drugs, the committee recommends the

Neuropathy and Chronic Inflammatory Demyelinating Polyneuropathy) are included in the preliminary list. While this represents a portion of our community, it excludes many other types of neuropathy.

The good news? The FDA is interested in public comments for those unrepresented disease areas. It is important that the FDA hears about the impact of all forms of neuropathy from patients, caregivers, health care professionals, and others in the community. Please consider submitting comments to the FDA to ensure neuropathy has a better chance of making 2016-2017 list!

[Click here to submit your comments online before December 5, 2014](#)

You can also submit written comments to the FDA. Be sure to include the identifier "ID: FDA - 2012-N-0967-0595":

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Don't miss this important opportunity to advocate for your health care needs and the needs of others in the neuropathy community!

Patient Education

Side Effects of IG Therapy: How to Prevent and Manage Them

By Cindy Berry, RN BSN

Immune Globulin (IG) therapy is used to treat many different diseases. Because the drug itself can have many side effects when administered, it is important for patients to understand what to do when facing side effects from therapy to ensure a treatment is well tolerated.

IG therapy can be given in a number of different ways. Depending on the disease being treated, patients may have a range of therapy from one day a month, to five days a month. Patients receiving larger doses may experience more side effects.

IG is known to have certain "expected" side effects, which patients can experience during and after their infusions. Expected effects are those that are the most common, and are considered mild side effects. They generally do not require medical intervention and can be easily managed. Although we "expect" some side effects, there are many ways to help decrease the severity and length of side effects by prevention and proper management.

Many physicians prescribe premedications to help decrease side effects. Usually, Tylenol (500 mg) and Benadryl (25-50 mg) are prescribed to take 30-60 minutes prior to the start of IG therapy. Taking both of these medications can help decrease infusion

Pennsylvania General Assembly push for implementation of the annual OOP cap within the ACA for essential services, and urges the state Legislature to consider legislation passed in Delaware and Maryland to cap OOP drug costs.

Montana Specialty Tiers Eliminated for 2015

Beginning in 2015, Insurance Commissioner Monica Lindeen is requiring the four largest insurance companies in Montana to provide equal coverage for all prescription medications. She is ending the discriminatory practice of classifying medications into specialty tier coverage. According to Ms. Lindeen, "Montanans managing MS or fighting cancer have enough to worry about. They shouldn't be hit with higher prescription drug costs on top of it." Some medications used to treat neuropathy also fall into the specialty tier.

Traditionally in Montana and other states across the nation, health insurance companies have grouped prescription drugs into tiers eliminating equality for certain classifications of prescriptions. Drugs lumped into a specialty tier are covered differently than other tiers in that they often require patients to pay thousands of dollars out of pocket in order to receive treatment medication. In the past, patients have had to pay the full deductible as well as a percentage of the cost of the prescription drug before receiving a prescription benefit. The end of specialty tier classifications makes affordable drug coverage available to those patients enduring painful and debilitating symptoms like those of neuropathy.

related side effects, as well as post-infusion related side effects. Tylenol helps to prevent low-grade fevers, flu-like symptoms, headaches and muscle spasms, while Benadryl helps decrease the body's response to the IG antibodies being introduced into a person's system. Usually, repeating premedications every 6 hours for 24 hours after the infusion can significantly help reduce most side effects.

Being well hydrated plays an important role when receiving IG therapy. Patients are encouraged to maintain good hydration status before, during and after their treatment. Drinking 1-2 liters of fluid a day, starting 24 hours prior to infusion and continuing throughout the infusion, as well as 24 hours post-infusion, is advised for most patients. Being well hydrated can help decrease headaches, which is one of the most common side effects reported from IG therapy. Good hydration will also help maintain good urine output, which is important for healthy kidney function.

Patients who have a history of migraines should inform their physician before initiating therapy. It may be important to take migraine medication prior to treatment to help prevent an onset of migraines.

During an infusion, some patients may experience infusion-related side effects that can be associated with the rate at which the drug is infused. Usually, if a patient experiences side effects during the infusion, it can be easily managed by the nurse. Many times, shutting off the drug for a period of time and then slowing the infusion can help prevent further side effects. Most patients report mild symptoms during the infusion such as chills/rigors, headache, nausea, back pain and/or low grade fever. If a patient is being infused and experiences any of these side effects, it is important to report this to the nurse at the onset of symptoms.

Following IG therapy, it is important to notify the physician if any serious side effects occur. These side effects include migraine headaches or severe headaches, tightness in chest, difficulty breathing, development of hives/rash, decreased urine output and/or dark colored urine.

Immune Globulin Therapy Side Effects

When receiving IG therapy - either by IV administration or subcutaneous administration, it is important to understand the difference between side effects that are expected and side effects that are not expected. Since side effects may have an onset after drug administration, it is important for the patient and/or caregiver to identify when to seek medical attention.

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The table below lists the most common side effects of IG therapy:

GREEN = expected and can be managed at home.

YELLOW = unexpected and needs to be reported. May need to seek medical intervention.

RED = MUST SEEK IMMEDIATE MEDICAL ATTENTION.

MILD SIDE EFFECTS <i>(considered "expected" side effects")</i>	Headache (pain rate 1-5/10), mild nausea (not interfering with daily routine), fatigue, flu-like symptoms, diarrhea, low grade fever (T < 101), itching skin, mild back pain/achiness, general fatigue.	Maintain good oral hydration. Repeat ordered premedication. Eat small meals. Try to rest when fatigue sets in. These side effects will subside after receiving current dose of Immune Globulin.
MODERATE SIDE EFFECTS <i>(not expected and considered reportable if experienced)</i>	Headache with pain report > 5/7, lasting more than 24 hours; nausea/vomiting interfering with daily activities, diarrhea lasting 24 hours or more, HIVES, fatigue affecting daily activities, decreased urine output or dark urine, new onset of swelling in feet.	These side effects are NOT expected. You may need changes in your treatment ordered by your doctor. Report these side effects to NuFACTOR as soon as possible: (800) 323-6832 X 1320 We will work with your physician to eliminate side effects
SEVERE SIDE EFFECTS <i>(MUST SEEK IMMEDIATE medical attention if experienced)</i>	Severe headache with pain reported as "intolerable" AND/OR severe headache with neck stiffness, sensitivity to light; chest pain, difficulty breathing, shortness of breath, uncontrollable vomiting/diarrhea, mental status change such as unresponsiveness. Fever > 101 degrees	Immediate medical attention is required. You must be evaluated by a local Emergency Room. Depending on symptom, either call 911 or have a family member/care giver drive to local ER. Report these side effects to NuFACTOR as soon as possible: (800) 323-6832 X 1320

[For more information visit IG Living Magazine.](#)

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