

On-Demand Clinical News

Medicare Part D Medication Coverage and the Hospice Benefit

Cody Midlam, Pharm.D., CGP

On Monday, March 10, 2014, the Centers for Medicare and Medicaid Services (CMS) issued a final guidance on the approval process for the Medicare Part D drug benefit when patients are also receiving the Medicare Hospice Benefit. This final rule follows a memorandum issued by CMS in December of 2013 to clarify the criteria for medication payment under the Medicare Part A (hospice) and Part D (drug) benefits.

The background of CMS' issuance of this policy is in response to a report from the U.S. Health and Human Resources (HHS) Office of Inspector General (OIG) which found potential duplications of payments from Medicare. Medicare pays hospices for a patient's hospice services—including hospice related drugs—under the Part A benefit, and Medicare pays pharmacies for senior citizens' drugs under the Part D benefit. The OIG felt they were duplicating payments by paying for medications with the Part D benefit when those should have been paid for by hospice under the Part A hospice benefit. The OIG found that in 2010, nearly fifteen percent of hospice enrollees had at least one analgesic paid for through Part D. The recent regulatory changes are, at least in part, due to these findings.

In the final guidance, CMS states, "For prescription drugs to be covered under Part D when the enrollee has elected hospice, the drug must be for treatment of a condition that is completely unrelated to the terminal illness or related conditions; in other words, the drug is unrelated to the terminal prognosis of the individual."

In response to this, Medicare Part D plans (ie: Cigna, Aetna, Blue Cross/Blue Shield) have been directed to place a beneficiary-level prior authorization (PA) process on all drugs for beneficiaries

Continued on page 3

Prolastin®-C Injection and Other Brand Name Alpha-1 Proteinase Inhibitors

Gerard M. McKeegan, R.Ph.

Prolastin®-C Injection is an alpha-1 proteinase inhibitor (A1PI), approved for chronic augmentation and maintenance therapy in adults with emphysema secondary to congenital alpha-1 proteinase inhibitor (A1PI) deficiency. In A1PI deficient patients, elastase produced by lung neutrophils can disrupt connective tissue in the lungs resulting in emphysema and obstructive lung disease. Typical symptoms of A1PI deficiency include shortness of breath, wheezing, rhonchi and rales. Patients with A1PI deficiency often develop emphysema during their thirties or forties, even without a significant smoking history. It can also cause impairment of liver function leading to cirrhosis and liver failure in 15% of patients. It has been estimated that about 1% of all COPD patients actually have A1PI deficiency.

Continued on page 2

Follow us Online & on Twitter!
(@PHCpharmacy)



Follow us online and on Twitter to keep up with the latest clinical news and regulatory trends that affect hospice care, or share your own exciting story!

The principal A1PI found in serum is alpha-1 antitrypsin (AAT) which is produced in the liver. One of its principal functions is to protect the lungs by inactivating elastase and protecting against the deterioration of lung function. Therefore the purpose of using Prolastin®-C and other purified A1PI solutions is to augment the body's natural levels of AAT, which may counter the effects of neutrophil elastase on lung tissue.

Alpha-1 Proteinase Inhibitor solutions are human derived protein products that include three brand name products that must be reconstituted before use: Prolastin®-C, Zemaira®, and Aralast NP® Injections. A newer, fourth product is Glassia® Injection, which does not require reconstituting. The recommended dose of Prolastin®-C and other brand name A1PI is 60 mg/kg body weight administered once weekly. The AWP (average wholesale cost) for available Alpha1-Proteinase Inhibitors ranges in cost from \$0.50 to \$0.58/mg. For a 70 Kg patient the usual dose would be 4,200 mg/week or ~\$2100/week or ~ \$8400/month.

Per the manufacturer's literature, Prolastin®-C Injection and the other brands of A1PI have demonstrated they raise the plasma level of Alpha-1 antitrypsin (AAT) but they are not a cure for A1PI deficiency. The effect of augmentation therapy with any A1PI on pulmonary exacerbations and on the progression of emphysema in A1PI deficiency has not been demonstrated in randomized, controlled clinical trials. These drugs are not indicated as therapy for lung disease in patients in whom severe A1PI deficiency has not been established. Prolastin®-C and other brand name A1PIs do not appear to be palliative care medications for an end of life patient being considered for Hospice Care, but that is a final decision to be made by each individual Hospice team based on the individual patient circumstances.

You can find a sample Prior Approval Criteria for Alpha-1 proteinase inhibitors (eg. Prolastin) updated in 12/2011 at this site:

http://www.fchp.org/~media/Files/FCHP/Imported/Prolastin_alpha1_antiproteinase_inhibitors.pdf.ashx

Hospices can call Prolastin Direct® at 800-305-7881 to have questions answered about insurance coverage, co-pays and delivery of PROLASTIN-C, as it is not available from local pharmacies and distribution is restricted to selected infusion providers.

References:

1. American Thoracic Society/European Respiratory Society Statement: "Standards for the Diagnosis and Management of Individuals With Alpha-1 Antitrypsin Deficiency," Am J Respir Crit Care Med, 2003, 168(7):818-900.[PubMed 14522813]
2. Louie SG, Sclar DA, and Gill MA, "Aralast: A New Alpha1-Protease Inhibitor for Treatment of Alpha-Antitrypsin Deficiency," Ann Pharmacother, 2005, 39(11):1861-9.[PubMed 16219903]
3. Stoller JK and Aboussouan LS, "Alpha1-Antitrypsin Deficiency," Lancet, 2005, 365(9478):2225-36.[PubMed 15978931]

Another Bright Idea to Save You Time!

Webinar: Solutions for Part D Prior Authorizations

Free Online Webinar – Choose the date that fits into your busy schedule and register today!

Wednesday, May 28th 2:30-3:30 PM/ET Registration URL: <https://attendee.gotowebinar.com/register/8611873506062149633>

Thursday, June 5th 12:00-1:00 PM/ET Registration URL: <https://attendee.gotowebinar.com/register/5882336989620509442>

Thursday, June 11th 12:00-1:00 PM/ET Registration URL: <https://attendee.gotowebinar.com/register/1355633324415563778>

Dr. Meri Madison & Dr. Ashley Provenzano will discuss solutions to save hospices time and money on Part D PAs.

You can also register online: www.ProCareHospiceCare.com

who are enrolled in hospice. 'Beneficiary-level' basically means if the patient is a hospice beneficiary, then all drugs that get billed at the pharmacy to the patient's Part D plan will require a prior authorization for payment. In other words, there will now be a second step—an authorization—to get those medications to process under a patient's Part D insurance.

To resolve the PA requirements, the hospice will need to provide documentation to the Part D plan that the particular medication is unrelated to the patient's terminal illness or related conditions. Hospices can either do this after there is a rejection at the pharmacy, or they can send a prior authorization notification proactively before any medications are processed at the pharmacy.

There is one additional component to this new regulatory process: medications that the hospice team feels are related to the terminal condition, but no longer effective would not be billed to the hospice or to the Part D plan, but rather would become the patient or family's responsibility. A few quick examples of these we commonly see may be statin drugs for reducing cholesterol in a patient with coronary artery disease, or acetylcholinesterase inhibitors (Aricept, Exelon Patch) used to treat Alzheimer's dementia when patients have end-stage dementia. In these instances, the medication is related to the terminal condition, but the medications may be deemed no longer necessary or effective. If the patient or caregivers prefers to continue the medication, in this case, they would maintain financial responsibility.

This recent CMS clarification is considered a final rule and the effective date of the policy change will be May 1, 2014. The guidelines can be accessed in their entirety online from CMS at the reference address below. Your ProCare HospiceCare team continues a vigilant watch for any regulatory changes, and is here to help you maintain compliance with all CMS directives. If you have any questions, please contact your ProCare HospiceCare Account Manager for additional information.

Reference:

Part D Payment for Drugs for Beneficiaries Enrolled in Hospice—Final 2014 Guidance. Tracey McCutcheon. Department of Health and Human Service, Center for Medicare and Medicaid Services. Accessed online March 24, 2014 at: <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/Hospice/Downloads/Part-D-Payment-Hospice-Final-2014-Guidance.pdf>

What Makes Some Pollen Cause Allergies, and Not Others?

- Plant pollens that are carried by the wind cause most allergies of the nose, eyes and lungs. These plants (including certain weeds, trees and grasses) are natural pollutants produced at various times of the year when their small, inconspicuous flowers discharge literally billions of pollen particles.
- Because the particles can be carried significant distances, it is important for you not only to understand local environmental conditions, but also conditions over the broader area of the state or region in which you live. Unlike the wind-pollinated plants, conspicuous wild flowers or flowers used in most residential gardens are pollinated by bees, wasps, and other insects and therefore are not widely capable of producing allergic disease.





Discontinuation of Namenda 5mg and 10mg Immediate Release Tablets

Cody Midlam, Pharm.D., CGP

Forest Laboratories, the manufacturer of NAMENDA® have announced that they will be discontinuing the sale of Namenda 5mg and 10mg strength tablets effective August 15, 2014. Generic versions of this product will be available in the spring of 2014. Until the generic formulations are available, the remaining formulations on the market will be Namenda liquid and Namenda XR, which is the extended-release formulation of Namenda tablets. Namenda XR is dosed once daily vs the twice-daily dosing regimen of the immediate-release tablets and it is indicated for the treatment of moderate to severe Alzheimer's disease.

The discontinuation of the immediate-release formulation means physicians may soon be required to switch their patients to the new product before the August deadline. According to the manufacturer, "physicians can switch patients from NAMENDA to NAMENDA XR the very next day without titration, as outlined in the FDA-approved package insert."

Another difference with the new formulation of Namenda is that the product is available in a capsule formulation. The manufacturer states, "NAMENDA XR capsules can be opened and the contents sprinkled on applesauce for patients who have difficulty swallowing pills." The dose of Namenda XR is also higher than that of its immediate-release counterpart. The target dose is Namenda XR 28mg daily, and patients are titrated up to this dose in 7mg increments no more frequently than once weekly.

Prior to considering conversion of your hospice patients from Namenda immediate-release to the new formulation of Namenda XR, it is recommended to review whether the medication is still considered effective and necessary for palliating the patient's end-of-life symptoms. There are no studies done which demonstrate Namenda is effective at end-of-life and it is generally recommended that the medication be discontinued once a patient is admitted to hospice for end-stage dementia.

An appropriate process is to taper the drug down slowly over the course of two weeks; if the patient has a decline in clinical status, or signs or symptoms of discomfort, the medication could be resumed at the previous dose. For example, if a patient is receiving Namenda immediate-release 10mg twice daily, a clinician could decrease the dose to 5mg twice daily for one week, re-evaluate symptoms, and if no clinically-significant decline in status is noted, further decrease to 5mg once daily, re-evaluate again, and then discontinue the medication.

References:

Forest Labs, Inc. Press Release. Forest Laboratories to Discontinue NAMENDA® Tablets, Focus on Once-Daily NAMENDA XR®. Accessed online at:

<http://investor.frx.com/press-release/business-development-news/forest-laboratories-discontinue-namenda-tablets-focus-once-d>

ProCare HospiceCare welcomes all suggestions and comments. If you would like additional information about our services, have ideas for articles, or wish to submit a comment, email us at resources@procarerx.com.

The information provided within this newsletter is proprietary to ProCare Rx. Any reprint or reuse of this information must be approved via written consent.

Copyright 2014, ProCare Rx



ProCare **HospiceCare**

1267 Professional Pkwy., Gainesville, GA 30507

Editor: Dr. Cody Midlam, PharmD, CGP

Executive Editor: Dr. Meri Madison, PharmD, CGP