THE TOOLS

Fast Facts

Deconstructing Claims Denials

- ✗ Hospital executives report that one in five claims submitted, on average, is delayed or denied and 96 percent of all claims must be submitted more than once.
- ✗ Insurance executives say they go back to hospitals two times, on average, to get all the information needed to pay a claim.
- ✗ Nearly a quarter of consumers reported having had a legitimate claim denied by their health plan; one in five ultimately paid the claim out of their own pocket.

Source: PNC Financial Services Group, Inc., healthcare industry survey of 200 hospital and insurance company executives and 1,000 U.S. consumers. The 2007 survey was conducted by the independent research firm Chadwick Martin Bailey.

PHOTOGRAPH/FOTOLIA

Approved Drugs

■ Eisai, Inc., and Pfizer, Inc., (Woodcliff Lake, N.J., and New York, N.Y.) announced that the Food and Drug Administration (FDA) has approved a new indication for **Fragmin® (dalteparin sodium injection)**, for the extended treatment of symptomatic venous thromboembolism (VTE) [proximal deep vein thrombosis and/or pulmonary embolism] to reduce the recurrence of VTE in patients with cancer. VTE is the formation of a blood clot that can travel from a leg vein to the lung, with potentially fatal results. Fragmin is the first low-molecular-weight heparin approved in the U.S. for the extended treatment of recurrent VTE in patients with cancer.

■ The FDA has approved **Torisel™ (temsirolimus)** for patients with advanced renal cell carcinoma. Wyeth Pharmaceuticals' (Collegeville, Pa.) product is the first targeted renal cell cancer therapy proven to extend median overall survival versus interferon-alpha, an active comparator, in this patient population. Renal cell carcinoma accounts for approximately 85 percent of kidney cancers. The American Cancer Society estimates that 51,190 new cases of kidney cancer will be diagnosed this year, and more than 40 percent of these patients are initially diagnosed with advanced disease. Torisel specifically inhibits the mTOR (mammalian target of rapamycin) kinase, a key protein in cells that regulates cell proliferation, cell growth, and cell survival.

Drugs in the News

■ MGI Pharma, Inc., and Helsinn Healthcare SA, (Minneapolis, Minn., and Lugano, Switzerland), have submitted a supplemental new drug application (sNDA) to the FDA for **Aloxi® (palonosetron hydrochloride) Injection** for the prevention of post-operative nausea and vomiting. Aloxi is approved by the FDA for the prevention of acute nausea and vomiting associated with initial and repeat courses of moderately and highly emetogenic cancer chemotherapy and for the prevention of delayed nausea and vomiting associated with initial and repeat courses of moderately emetogenic cancer chemotherapy.

■ The FDA has granted DUSA Pharmaceuticals, Inc., (Wilmington, Mass.) orphan drug designation for **Levulan® (aminolevulinic acid HCl) Photodynamic Therapy** for the treatment of esophageal dysplasia. This disease occurs in patients with Barrett's esophagus, a leading cause of esophageal cancer. Patients diagnosed with high-grade dysplasia are at high risk for developing esophageal cancer and currently have limited treatment options.

Photodynamic therapy is a photochemical process that involves the interaction of a photosensitizer, light, and oxygen to selectively destroy malignant or certain benign, but rapidly growing cells.

■ SuperGen, Inc., (Dublin, Calif.) received FDA clearance to initiate a first-in-human Phase I clinical trial with **MP470**, an oral multi-targeted tyrosine kinase inhibitor (TKI). The Phase I accelerated titration dose-escalation trial will assess the safety and tolerability of MP470 and determine the maximum tolerated dose. Pharmacokinetic and biomarkers data will also be collected and assessed to assist in designing follow-on clinical studies for the use of MP470 as a single agent and in combination treatment modalities.

MP470 is a oral selective multi-targeted TKI that inhibits MET, RET, and the mutant forms of KIT, PDGFR, and FLT3, as well as suppresses the Rad51 protein, a critical component of double-stranded DNA repair in cancer cells.

■ Cell Therapeutics, Inc., (Seattle, Wash.) has received fast track designation from the FDA for **pixantrone**, a novel anthracenedione, being investigated for the potential treatment of relapsed or refractory indolent non-Hodgkin's lymphoma. Pixantrone is an investigational agent under development for the potential treatment of various hematological malignancies, solid tumors, and immunological disorders. It was developed to improve the activity and safety of the anthracycline family of anti-cancer agents.

■ Pharmacyclics, Inc., (Sunnyvale, Calif.) has filed a new drug application (NDA) with the FDA for **Xcytrin® (motexafin gadolinium) Injection**. The company is seeking approval to

market the drug for the treatment of non-small cell lung cancer patients with brain metastases. Xcytrin is a redox-active drug that has been shown to disrupt redox-dependent pathways in cells and inhibit oxidative stress related proteins.

■ Exelixis, Inc., (South San Francisco, Calif.) has submitted an investigational new drug (IND) application to the FDA for **XL765**. In preclinical studies, the molecule has been shown to inhibit the activity of phosphoinositide-3 kinase (PI3K), which is frequently activated in tumors and promotes cell growth, survival, and resistance to chemotherapy and radiotherapy. In addition, XL765 inhibits the mammalian target of rapamycin (mTOR), which is activated frequently in human tumors and plays a central role in tumor cell growth.

The company has also submitted an IND application to the FDA for **XL019**. In preclinical studies, the compound has been shown to be an inhibitor of the cytoplasmic tyrosine kinase JAK2.

Devices in the News

■ **Cavity SpineWand®** (ArthroCare, Sunnyvale, Calif.) has received FDA clearance to treat malignant lesions within the vertebrae. The device is used in a minimally invasive, surgical procedure to remove malignant tissues within the vertebrae. In this spine procedure, an interventional radiologist or neurosurgeon in consultation with a radiation oncologist, creates a small incision and inserts a cannula to access the affected area within the spine. This procedure does not eliminate other therapeutic options for the patient, such as radiation or chemotherapy.

■ Avantis Medical Systems, Inc., (Sunnyvale, Calif.) has received FDA clearance to market its **Third Eye™ Retroscope™ Auxiliary Endoscopy System**. The imaging device is used during colonoscopy to provide an additional view that can reveal polyps, cancers, and other lesions that might be missed during a standard colonoscopy procedure. The Third Eye Retroscope is passed through the instrument channel of a standard colonoscope until it extends beyond its tip. As it emerges, the device turns around 180 degrees to aim back toward the tip of the colonoscope. Then, as the colonoscope is withdrawn, the Third Eye follows along to provide a continuous retrograde view of the colon. This retrograde view complements the forward view of the colonoscope and may reveal abnormalities that are hidden behind folds and flexures.

Genetic Tests, Assays, and Vaccines in the News

■ AutoGenomics, Inc., (Carlsbad, Calif.) has obtained FDA clearance to market its **Infiniti Analyzer** as stand alone instrumentation for multiplexed assays. The company has already submitted another 510(k) application to the FDA for its **Infiniti 2C9/VKORC1 Multiplexed Assay** to assess Warfarin sensitivity.

Cytogen Raises Awareness about Oral Mucositis

Recently, Cytogen Corporation (Princeton, N.J.) established an expanded market presence for **Caphosol®**, an advanced electrolyte solution indicated in the U.S. as an adjunct to standard oral care in treating oral mucositis (OM) caused by radiation or high-dose chemotherapy. Caphosol, a prescription medical device, is also indicated for dryness of the mouth or throat (hyposalivation, xerostomia), regardless of the cause or whether the conditions are temporary or permanent. Because it is isotonic with normal human saliva, Caphosol can restore the normal ionic and pH conditions of the oral cavity.

As part of its commitment to advancing the treatment and care of cancer patients, Cytogen launched CARE OM, *www.careom.com*, a web-based education and support center for patients and caregivers seeking to learn more about OM and Caphosol. In addition to oral mucositis educational material and support information, visitors to CARE OM can also download an OM brochure or request a free brochure about OM by mail.

Cytogen reports that in a recent survey of 427 past and present oral mucositis sufferers:

- An overwhelming majority of respondents (N=363; 85%) said there is a lack of information available about oral mucositis.
- One out of four (N=108; 25%) respondents did not find anything to relieve their OM symptoms.
- An overwhelming majority (N=384; 90%) of cancer patients agree that oral mucositis adversely affects their quality of life.

Sanofi-aventis Announces PACT+ Provider Portal

PACT+ (Providing Access to Cancer Treatments) **Provider Portal** is a secure website accessible only to healthcare providers and reimbursement personnel who participate in the PACT+ program on behalf of their practice's needy patients. This oncology tool offers improved workflow processes related to reimbursement and patient assistance program information, such as the ability to: streamline and prioritize PAP caseload; complete enrollment applications online; receive alerts and reminders about specific patient cases; track PAP product shipments; and easily access all patient-related information, including patient history, alerts/reminders, insurance benefit summaries, shipments, attachments, and case history. To register for the PACT+ Provider Portal, please visit *www.pactplusonline.com* or call 800.996.6626. There are no charges associated with registration or use of this portal.