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Approved Drugs

- The U.S. Food and Drug Administration (FDA) approved Genentech's *(www.gene.com)* **Kadcyla (ado-trastuzumab emtansine)**, a new therapy for patients with HER2-positive, late-stage breast cancer. Kadcyla is intended for patients who were previously treated with trastuzumab, another anti-HER2 therapy, and taxanes, a class of chemotherapy drugs commonly used for the treatment of breast cancer.

- The FDA approved Celegene's *(www.celgene.com)* **Pomalyst (pomalidomide)** to treat patients with multiple myeloma whose disease progressed after being treated with other cancer drugs. Pomalyst is a pill that modulates the body's immune system to destroy cancerous cells and inhibit their growth. It is intended for patients who have received at least two prior therapies, including lenalidomide and bortezomib, and whose disease did not respond to treatment and progressed within 60 days of the last treatment (relapsed and refractory).

- Bayer Healthcare *(www.bayer.com)* and Onyx Pharmaceuticals *(www.onyx.com)* announced that the FDA expanded the approval of **Stivarga (regorafenib) tablets** to treat patients with locally advanced, unresectable, or metastatic gastrointestinal stromal tumors (GIST) who have been previously treated with imatinib mesylate and sunitib malate.

Drugs in the News

- Janssen Research & Development, LLC *(www.janssenrnd.com)*, announced that the FDA has granted breakthrough therapy designations for the investigational oral agent **ibrutinib** as a monotherapy for two B-cell malignancies: in patients with relapsed or refractory mantle cell lymphoma who have received prior therapy, and in patients with Waldenstrom's macroglobulinemia.

- The FDA has granted orphan drug designation to Eisai Inc. *(www.us.eisai.com)* for its investigational drug **lenvatinib (E7080)** for follicular, medullary, anaplastic, and metastatic or locally advanced papillary thyroid cancer.

- Lentigen Corporation *(www.lentigen.com)* announced that the FDA has granted orphan drug status to **P140K methylguanine methyltransferase (MGMT) transduced human CD34** cells (product name: LG631-CD34) for bone marrow protection in the treatment of glioblastoma multiforme.

Approved Devices

- Royal Philips Electronics *(www.philips.com)* announced 510(k) clearance from the FDA for its **MicroDose SI system**, a full-field digital mammography (FFDM) system with the capability to enable future single-shot spectral imaging applications.

- Elekta *(www.elekta.com)* received 510(k) clearance from the FDA allowing the company to begin shipping and installation of all components of the **Versa HD™ system** within the United States. Fully integrated with the Agility™ 160-leaf multileaf collimator (MLC), Versa HD provides high-definition, high-speed beam shaping over a 40 X 40 cm field.

OPPS Payment Rates for SRS Services

CPT/HCPCS CODE RATE	LONG DESCRIPTOR	APRIL 2013 APC	APRIL 2013 PAYMENT
77371	Radiation treatment delivery, stereotactic radiosurgery (SRS), complete course of treatment of cranial lesion(s) consisting of 1 session; multi-source Cobalt 60 based	0127	$7,911 (Rural hospitals and other excepted hospitals) $3,301 (All other hospitals)
G0173	Linear accelerator based stereotactic radiosurgery, complete course of therapy in one session	0067	$3,301

Source. CMS Manual System. Pub 100-04 Medicare Claims Processing. Transmittal 2664.