



STATE MEDICAID P&T COMMITTEE MEETING
THURSDAY, September 16, 2012
7:00 a.m. to 8:30 a.m.
Cannon Health Building
Room 114



MINUTES

Committee Members Present:

Ellie Brownstein, M.D.
 Kort Delost, R.Ph.
 Lisa Hunt, R.Ph.

Roger Martenau, M.D.
 Julia Ozbolt, M.D.
 Bernadette Kiraly, M.D.

Dept. of Health/Div. of Health Care Financing Staff Present:

Robyn Seely, Pharm.D.
 Tim Morley, R.Ph.

Rick Sorenson, R.N.

University of Utah Drug Information Center Staff Present:

Melissa Archer, Pharm.D.

Gary Oderda, Pharm.D.

Other Individuals Present:

Kristi Adams GSK
 Lori Howarth Bayer
 KaeLynn Nielsen unaffiliated
 Joe Borgham BMS
 Sunil Sharma Huntsman Cancer Institute
 Theresa Warner Huntsman Cancer Institute
 Charissa Anne J&J

Scott Goldfarb GSK
 Tien Nguyen Bayer
 Scott Larson BMS
 Alan Bailey Pfizer
 Lori Blackner Pfizer
 William Yoon Novartis

Meeting conducted by Ellie Brownstein

- 1 Review and Approval of Minutes: Kort Delost made a motion to approve the July minutes. Bernadette Kiraly seconded the motion. The motion was approved unanimously.
- 2 Update on PDL Administration: Lisa Hunt informed the Committee that she will be meeting with Michael Hales, Director of the Department of Health, to formally add the sedative/hypnotic drugs to the Preferred Drug List (PDL).
 - a. On October's agenda is a review of topical steroids. Further scheduling will be determined at a later time, with recommendations from the University of Utah Drug Regimen Review Center.

Utah Medicaid's PDL afforded a savings of \$35.9 million last year. Lisa thanked the Committee for their expertise and time. Lisa briefly described the purpose of the PDL, the Prior Authorization (PA) process, availability of PA criteria, the rebate program, and reminded everyone that drugs that are not on the PDL can be reimbursed with a PA.

Lisa described other states' treatment of the anti-neoplastic classes of drugs: Preferred Drug Lists, Recommended Drug Lists (RDLs), the complete inclusion of all anti-neoplastic drugs with no PA requirements, and other policies

Lisa reminded the Board and guests to sign in.

Lisa made a short statement regarding the creation of Accountable Care Organizations (ACOs) in January 2013. It is unknown if and how each ACO will "grandfather" the PAs of patients that previously had approval for reimbursement of drug requiring PA.

- 3 Drug Utilization Review (DUR) Board update: Robyn Seely addressed the committee. She reported that the DUR board last met on Thursday September 14, 2012. Tablet limits were discussed, as were interactions between amlodipine and other QT-prolonging drugs. Interactions between citalopram and ondansetron were discussed. October's agenda includes more information regarding citalopram and ondansetron use, and a review of modafinil and armodafinil PA criteria.

4 **Antineoplastic Tyrosine Kinase Inhibitors**

- a. Melissa Archer provided an overview of the thirteen available tyrosine kinase inhibitors and their different indications. The efficacy of each product was analyzed, with consideration given to the National Comprehensive Cancer Network (NCCN). The University of Utah Drug Information Center recommended including all tyrosine kinase inhibitors on a Recommended Drug List, or to include all tyrosine kinase inhibitors on a Preferred Drug List (PDL).
- b. Ellie Brownstein asked about other states' policies. Lisa described Iowa's RDL and Maine's PDL. Wyoming does not require any PA on any tyrosine kinase inhibitor, but does require the use of a specialty pharmacy to obtain them.
- c. Public Comment:
 - i. William Yoon, Pharm.D., from Novartis discussed the role of imatinib (Gleevec®) in the treatment of Philadelphia chromosome-positive chronic myeloid leukemia (Ph+ CML), and other disease states for which Novartis seeks to develop treatments. Kort DeLost asked William Yoon to clarify the various indications for imatinib. William Yoon listed the following indications: kit-positive gastrointestinal stromal tumors CD117 GIST), Ph+ CML in chronic phase, acute phase and in blast crisis, aggressive systemic mastocytosis (ASM), dermatofibrosarcoma protuberans (DFSP), hypereosinophilic syndrome (HES), chronic eosinophilic leukemia (CEL), and myelodysplastic/myeloproliferative disease (MDS/MPD).
 - ii. Joseph Brougham, Pharm.D., from Bristol-Myers Squibb, discussed the

dasatinib's (Sprycel®) three indications: First-line treatment of Ph+ CML in chronic phase, acute phase and in blast crisis; Second-line treatment (after imatinib failure) of Ph+ CML in chronic phase, and of Philadelphia-chromosome positive acute lymphoblastic leukemia (Ph+ ALL).

Bernadette Kiraly asked if dasatinib was indicated for pediatric Ph+ ALL. Joseph Brougham stated that it is approved only for adults, but that research regarding pediatric populations is underway. Melissa drew the Committee's attention to a Table in her report regarding pediatric use in the Utah Medicaid population. In the past three years, Utah Medicaid has reimbursed dasatinib prescriptions for six distinct pediatric patients.

- iii. Kae Lynn Nielson, a beneficiary of private insurance, who has been diagnosed with lymphoma, discussed her treatment regimen.
 - iv. Tien Nguyen, Pharm.D., from Bayer, discussed recent changes to sorafenib's (Nexavar®) package insert. Sections 5.4 (Warnings and Precautions: Risk of Dermatologic Toxicities), 5.9 (Warnings and Precautions: Risk of QT interval Prolongation), 5.10 (Warnings and Precautions: Drug-Induced Hepatitis), and 6.3 (Adverse Reactions: Additional Data from Multiple Clinical Trials) have recently been updated.
 - v. Sunil Sharma, M.D., of the Huntsman Cancer Institute, was accompanied by Theresa Warner, M.D. They discussed the complexity of cancer treatments, and the utility of the NCCN's guidance. Sunil Sharma and Theresa Warner treat many Utah Medicaid patients. Ellie Brownstein asked what percentage of cancer patients are treated according to NCCN guidelines. Sunil Sharma estimates that about 90% of treatments follow the guidelines because ad hoc management of individual cancer cases is too complex to devise a unique regimen for each. Robyn Seely asked Sunil Sharma and Theresa Warner if they have experienced denied PAs for their Medicaid patients. Sunil Sharma and Theresa Warner said that they had not had trouble with Utah Medicaid, but that there is substantial difficulty with private insurers.
- d. Board Discussion/Questions: Ellie Brownstein commented on the complexity of cancer treatments. Bernadette Kiraly noted that indications for tyrosine kinase inhibitors continue to broaden, and putting restrictions on them, based upon indication, might be unreasonable. Ellie Brownstein stated an opinion that the NCCN guidelines are rigorously reviewed and can be trusted.
- e. Board Action:
- i. Ellie Brownstein moved that although each tyrosine kinase inhibitor has the potential for substantially detrimental adverse effects, they are reasonably safe and effective in their overlapping indications. Kort DeLost seconded the motion and the motion was approved unanimously.
 - ii. Ellie Brownstein suggested that all of the tyrosine kinase inhibitors should be preferred, and Bernadette Kiraly made the motion. Julia Ozbolt seconded the motion and the motion was approved unanimously.

The next Pharmacy and Therapeutics Committee meeting is scheduled for Thursday, October 18, 2012.

Meeting Adjourned.

Minutes prepared by Robyn Seely.