Pharmacy and Therapeutics (P&T) Committee Meeting
February 16, 2016
6:00 PM – 8:00 PM
MINUTES

P&T Committee Members
Matthew Flynn, MD
Randy Grigg, MD
Kenneth Kohagen, MD
David Konanc, MD
Sheila Marshall, DO
Jennifer Smith, PharmD
Michael Spiritos, MD

State Health Plan (SHP) Staff
David Boerner, MD (Co-chair)
Lotta Crabtree, JD
Natasha Davis
Adam Root, PharmD (Co-chair)
Sandra Wolf
Neha Zadoo

SHP Contracted Vendors
Ryan Kondritz, PharmD (Express Scripts)

Guests
Emily Ghassemi, PharmD (Campbell University)

I. Welcome and Conflict of Interest

Dr. Adam Root and Dr. David Boerner welcomed the committee members and guests.

Dr. Root reviewed the SHP Ethics Awareness and Conflict of Interest Policy. No conflicts were disclosed for any of the medications discussed.

II. Minutes from November 17, 2015 Meeting

The committee members reviewed and approved the November 17, 2015 minutes.

III. Old Business – PA Program Updates

Dr. Root discussed the following updates to the SHP pharmacy utilization management programs for the Traditional and Consumer-Directed Health Plan Benefits.

Policy	Revision
Seroquel Prior Authorization Policy	• New policy promoting appropriate use of low dose quetiapine and quetiapine XR
Weight Loss Prior Authorization Policy	• Policy updated to add step requirement for trial and failure of generic phentermine prior to brand products (excluding Xenical)
Testosterone Prior Authorization Policy	• Existing policy was separated into two polices: injectable and oral & topical and nasal • Added a requirement for two testosterone confirmatory tests and removed anabolic steroids
Hepatitis C Policies	• Updated Harvoni, Daklinza, Sovaldi, Viekira Pak, and Olysio policies to reflect national guidelines. • Updated Technivie policy to add requirement for a trial of Harvoni
Ilaris Prior Authorization Policy	• Policy updated to allow allergists/immunologists to prescribe. • Extended PA approval to 3 years.
Arcalyst Prior Authorization Policy	• Policy updated to allow allergists/immunologists to prescribe. • Extended PA approval to 3 years.
Growth Hormone PA/ST Policy	• Removed Tev-Tropin (no longer marketed) and added Zomacton
Juxtapid Prior Authorization Policy	• New policy to review FDA indication (HoFH) and requirement for the trial of Repatha, a PCSK9 inhibitor
Kynamro Prior Authorization Policy	• New policy to review FDA indication (HoFH) and requirement for the trial of Repatha, a PCSK9 inhibitor
Orencia Prior Authorization Policy	• Policy updated to remove limitation to adult prescribing in RA • Moved psoriatic arthritis to exclusion. • Updated the PA approval to initial 3-month approval followed by 3 years.
Enbrel Prior Authorization Policy	• Policy updated to align with ESI standard policy. Added criteria for SpA and undifferentiated spondyloarthritis and reactive arthritis. • Added autoimmune mucocutaneous blister diseases, PMR, and Giant Cell arteritis to exclusion.
Humira Prior Authorization Policy	• Policy updated to align with ESI standard policy. • Added new indication for Hidradenitis supportive. • Added criteria for SpA and an exclusion for PMR.
Odomzo Prior Authorization Policy	• New policy to review for FDA indication basal cell carcinoma after all surgical and radiation therapies have been utilized.
Erivedge Prior Authorization Policy	• New policy to review for FDA indication basal cell carcinoma after all surgical and radiation therapies have been utilized.
Nucala Prior Authorization Policy	• New policy to review for FDA indication (severe asthmatics with eosinophilic genotypes)

Additionally, Dr. Boerner updated the P&T members on the Nucala Prior Authorization policy, including the small subset of asthma patients who this product will be used in and the requirement for an eosinophil level prior to approval.

Executive Session (closed session)

IV. Program Reviews and Opportunities

Stivarga Prior Authorization Policy
Dr. Michael Spiritos reviewed the prior authorization policy for Stivarga (regorafenib tablets) indicated for metastatic colorectal cancer (mCRC) in patients who have been previously treated with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy, an anti-vascular endothelia growth factor (VEGF) therapy, and, if *KRAS* wild-type, an anti-epidermal growth factor receptor (EGFR) therapy. Stivarga is also indication for the treatment of patients with locally advanced, unresectable or metastatic gastrointestinal stromal tumor (GIST) who have been previously treated with imatinib and sunitinib. Dr. Spiritos explained that this medication is much like other kinase inhibitors and would be used as a fourth to fifth line option in patients healthy enough for therapy.

Lonsurf Prior Authorization Policy
Dr. Spiritos reviewed the prior authorization policy for Lonsurf (trifluridine and tipiracil tablets) indicated for metastatic colorectal cancer (mCRC) in patients who have been previously treated with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy, an anti-vascular endothelial growth factor (VEGF) biological therapy, and if *RAS* wild-type, an anti-epidermal growth factor receptor (EGFR) therapy. Dr. Spiritos explained that much like Stivarga, Lonsurf will be used as a fourth to fifth line option in patients healthy enough for therapy.

Cotellic Prior Authorization Policy
Dr. Spiritos reviewed the prior authorization policy for Cotellic (cobimetinib) indicated in combination with Zelboraf (vemurafenib) for the treatment of patients with unresectable or metastatic melanoma with the BRAF V600E or V600K mutation. Dr. Spiritos explained that this resembles another combination already on the market, Tafinlar (dabrafenib) and Mekinist (trametinib), and will likely compete for market share.

Keveyis Prior Authorization Policy
Dr. David Konanc reviewed the prior authorization policy for Keveyis (dichlorphenamide tablets) indicated for the treatment of primary hyperkalemic periodic paralysis (HyperPP), primary hypokalemic periodic paralysis (HypoPP), and related variants. . Dr. Konanc relayed to the committee that the criteria put forward is appropriate and that the State Health Plan is unlikely to see more than one patient/year requiring this treatment.

Daraprim Prior Authorization Policy
Dr. Root reviewed the prior authorization policy for Daraprim (pyrimethamine tablets) indicated for the treatment of toxoplasmosis (when used in conjunction with a sulfonamide), treatment of acute malaria (when used in conjunction with another medication), and chemoprophylaxis of malaria. Dr. Root explained that the reason for the review of this older medication was because of the dramatic price increase that occurred over the past several months. Dr. Root reviewed the prior authorization criteria for Daraprim and explained that it mirrored current guideline recommendations. Additionally, patients

will be able to obtain a 2 week supply of therapy, if the prescriber is unable to be contacted for approval of the prior authorization.

V. New Drug Reviews

Criteria for Must Add, May Add and Must Not Add
Dr. Root reminded the committee about the criteria used to determine whether a drug should be considered a "Must Add", "May Add" or "Must Not Add" to the State Health Plan Traditional Pharmacy Benefit Preferred Drug List (PDL) (this does not apply to the Consumer Directed Health Plan (CDHP) since that plan does not have a preferred drug list). This list, derived from ESI's P&T, should be used by the committee as a helpful resource to guide the committee's decisions. Dr. Root updated the committee on the new copays for the 70/30 plan for 2016. The Must Add to SHP preferred drug list has a $46 co-payment tier for 70/30, and $40 copayment tier for 80/20, May Add to the SHP preferred drug list has either a $46 (70/30) or $40 (80/20) co-payment tier or a $72 (70/30) or $64 (80/20) co-payment tier, and Must Not Add to SHP preferred drug list has a $72 (70/30) or $64 (80/20) co-payment tier.
The following drugs were reviewed. The committee's comments and decisions are recorded below:

Synjardy® (empagliflozin and metformin tablets)
Synjardy, a combination of empagliflozin, a sodium-glucose co-transporter (SGLT2) inhibitor and metformin, a biguanide, is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus who are not adequately controlled on a regimen containing empagliflozin or metformin, or inpatient already being treated with both empagliflozin and metformin.

*Dr. Jennifer Smith reviewed this drug with the committee and recommended that Synjardy be **designated a "May Add"** to the State Health Plan Traditional Pharmacy PDL. Synjardy is another combination product that may have better safety data than other SGLT2 products on the market and a demonstrated decreased risk for CV-events.*

Tresiba® (insulin degludec injection)
Tresiba is a long-acting basal human insulin analog indicated to improve glycemic control in adults with diabetes mellitus.

*Dr. Adam Root reviewed this drug with the committee and recommended that Tresiba be **designated a "May Add"** to the State Health Plan Traditional Pharmacy PDL. Tresiba demonstrated non-inferiority to other basal insulins on the market with a potential decrease in nocturnal hypoglycemia. Dr. Smith added that Tresiba may have an advantage in patients who do not have good adherence as Tresiba can be given any time of day, and did not demonstrate any significant differences in hypoglycemia events when missed doses were given later. Dr. Root added that a step-therapy or prior authorization be considered, requiring preferred agents, Lantus and Levemir, prior to treatment.*

Viberzi™ (eluxadoline tablets)
Viberzi, a mu-opioid receptor agonist, is indicated in adults for the treatment of irritable bowel syndrome with diarrhea (IBS-D).

*Dr. Kenneth Kohagen reviewed this drug with the committee and recommended that Viberzi be **designated a "Must Add"** to the State Health Plan Traditional Pharmacy PDL. Viberzi adds another*

therapy to the limited amount of products indicated for diarrhea predominant irritable bowel syndrome which is much less common than constipation predominant.

Envarsus XR® (tacrolimus extended-release tablets)
Envarsus XR is indicated for the prophylaxis of organ rejection in kidney transplant patients converted from tacrolimus immediate-release formulations, in combination with other immunosuppressants.

*Dr. David Boerner reviewed this drug with the committee and recommended that Envarsus XR be **designated a "May Add"** to the State Health Plan Traditional Pharmacy PDL. Envarsus XR is only indicated in patients already stable on tacrolimus immediate-release formulations with kidney transplant, which limits its use and is purely for convenience versus increased efficacy/safety.*

Vraylar™ (cariprazine capsules)
Vraylar, an atypical antipsychotic, is indicated for the treatment of schizophrenia and the acute treatment of manic or mixed episodes associated with bipolar 1 disorder.

*Dr. Randy Grigg reviewed this drug with the committee and recommended that Vraylar be **designated a "May Add"** to the State Health Plan Traditional Pharmacy PDL. Vraylar appears to be as efficacious as other therapies on the market and showed separation from placebo in improved Young Mania Rating Scale for acute episodes which is better than current therapies. Vraylar does not yet have the long term data to assess for differences in lipids and other safety concerns.*

Tolak® (fluorouracil 4% cream)
Tolak is indicated for the topical treatment of actinic keratosis lesions of the face, ears, and/or scalp.

*Dr. Matthew Flynn reviewed this drug with the committee and recommended that Tolak be **designated a "May Add"** to the State Health Plan Traditional Pharmacy PDL. Tolak cream contains peanut oil which may aid in the erythema, scaling and dryness associated with fluorouracil topical products, but it has not been evaluated against other therapies.*

VI. Other Topics

Specialty Generic Tier
Sandy Wolf presented an update from the Board of Trustees meeting in which a new specialty tier was approved. This will increase the current five-tier structure to a six-tier structure as demonstrated below:

- Traditional Tiers: Tier 1-preferred generics, Tier 2-preferred brands and high cost generics, Tier 3-non-preferred brands
- Specialty Tiers: Tier 4-generic specialty, Tier 5-preferred brand specialty, Tier 6-non-preferred brand specialty

Specialty Medication from Medical to Pharmacy Benefit
Sandra Wolf presented another update from the Board of Trustees meeting in which the transition of specialty products from the medical to pharmacy benefits was approved. This will be completed in three phases, the first phase being self-administered and hemophilia/IVIG drugs, followed by remaining rare diseases, and then physician administered products. Questions were asked regarding patients who may be better suited to receive care within the clinic setting, with the response being that these patients would be allowed to continue therapy there if the appropriateness was determined by ESI. Additionally, ESI has a large number of home health nurses already practicing in the state of NC ready to take on the

SHP patient population. Before moving to additional phases of the project, physician concerns and comments will be addressed.

2016 Meeting Dates

Dr. Adam Root presented the following dates for the 2016 P&T Committee Meetings:

- May 10, 2016
- August 9, 2016
- November 8, 2016

The next meeting is scheduled for May 10, 2016.