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Pharmacy Services
San Francisco Health Plan Pharmacy & Therapeutics Committee

Wednesday, January 18, 2017
7:30AM – 9:30AM
50 Beale St., 13th Floor, San Francisco, CA 94119

Meeting called by:	James Glauber, MD	**Minutes Takers:** Sheila Zeno, CPhT (SFHP Analyst, Pharmacy Services)
Meeting Objective:	Vote on proposed formulary and PA criteria changes	**Type of meeting:** Quarterly
Attendees:	**Voting Members:** James Glauber, MD (SFHP Chief Medical Officer) Lisa Ghotbi, Pharm. D (SFHP Director of Pharmacy) Shawn Houghtaling, Pharm. D. Nicolas Jew, MD Ted Li, MD Joseph Pace, MD Ronald Ruggiero, Pharm. D Linda Truong, Pharm. D. Steven Wozniak, MD	**Others Present:** Andrew Costiniano, CPhT (SFHP Specialist, Pharmacy Services) Grace Dadios (SFHP Health Services Department Specialist) Olga Mostovetsky, Pharm. D (SFHP Clinical Pharmacist, Pharmacy Services) Keira Truong, Pharm. D (SFHP Pharmacy Resident, Pharmacy Services) Jenna Heath, Pharm. D (PerformRx Clinical Pharmacist) Kim Foerster (Excelsior Solutions) Jennifer Denning (Bristol-Myers Squibb)
Members Absent:	Roger Tiao, Pharm. D Jamie Ruiz, MD Robert (Brad) Williams, MD	
Meeting Materials: Jan2017PTBinde...	Summary of all approved changes are posted under "Materials" section at http://www.sfhp.org/providers/formulary/pharmacy-therapeutics-committee/ SFHP formulary is located at http://www.sfhp.org/providers/formulary/sfhp-formulary/ SFHP prior authorization criteria are located at http://www.sfhp.org/files/providers/formulary/Prior_Auth_Criteria.pdf	

	Topic	Brought By	Time/ Duration	Discussion	Action
1.	Call to Order and Instructions	James Glauber		The meeting was called to order at 7:30am.	
2.	Agenda overview and other topics	James Glauber	2 mins	Introduction agenda topics.	

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3.	Informational Updates	James Glauber	2 mins	• De-delegated Healthy Workers pharmacy benefit on 12/1/16. Reported a smooth transition for members. • SFHP received an outstanding award for a health plan. Best public Medi-Cal plan in the state. Best in Quality outside of Kaiser.	
4.	Review and Approval of October 19, 2016 P&T Minutes	James Glauber	2 mins	The committee had no corrections to the minutes.	**VOTES:** **Review and Approval of Oct 19, 2016 P&T Minutes** 8 approved, 0 denied, 0 abstained *Motion*: Nicolas Jew ***1 expected attendee was absent during the vote.*
	******Adjourn to Closed Session****** Closed Session pursuant to Welfare and Institutions Code Section 14087.36 (w)				
5.	Discussion and Recommendation for Changes to SFHP Formulary and Prior Authorization Criteria for Select Drug Classes **Hematology** • Erythropoietin Stimulating Agents (P13-24 Jan of 2017 P&T Packet) • Iron Replacement (abbreviated) (P25-28 Jan of 2017 P&T Packet) • Thrombopoietin Receptor Agonists (P29-36 Jan of 2017 P&T Packet) • White Blood Cell Stimulators (P37-48 Jan of 2017 P&T Packet)	Keira Truong Olga Mostovetsky	20 mins	The plan presented therapeutic review and recommendations for Hematology medications. Major recommendations included the following: **Erythropoietin Stimulating Agents:** • No changes for formulary placement • Revised PA criteria for cancer/chemo-therapy induced anemia to incorporate excluded patient populations per National Comprehensive Cancer Network (NCCN) guidelines. • Consolidated Aranesp® and Epogen®/Procrit® criteria and added Mircera® to criteria. The committee inquired why Mircera® is not being used considering its cost effectiveness compared to the other ESA agents. The plan responded that even though Mircera® has been available for many years, it has not been incorporated into any practice guidelines and this could be the reason for its lack of use in clinical practice. **Iron Replacement Products:** The following medications were added to formulary: • Slow Release iron 45 mg tablet • Ferrous sulfate 220 mg/5 ml elixir • Ferrous gluconate 325 mg tablet	**VOTES:** **Hematology** ***EPO:*** 9 approved, 0 denied, 0 abstained *Motion:* Ted Li ***Iron Replacement:*** 9 approved, 0 denied, 0 abstained *Motion:* Ron Ruggiero ***Thrombopoietin:*** 9 approved, 0 denied, 0 abstained *Motion:* Lisa Ghotbi ***White Blood Cell stimulators:*** 9 approved, 0 denied, 0 abstained *Motion:* Nicolas Jew

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				The committee had no comments or questions. **Thrombopoietin Receptor Agonists**: No changes were recommended to formulary placement. The following changes were recommended to PA criteria: • Update criteria to include additional labeled indications for Promacta®: severe aplastic anemia and thrombocytopenia associated with HCV infection. • Update criteria for diagnosis of chronic immune (idiopathic) thrombocytopenia (ITP) to include Rituxan® as prior treatment option. • Add Nplate® to criteria. Committee inquired whether for indication of ITP, all alternative therapies are required prior to approval of Promacta® and Nplate® or only one. Plan responded that only one prior therapy is required and will clarify this point in PA criteria. **White Blood Cell stimulators***:* • Add Zarxio™ to formulary with prior authorization and prefer to Neupogen® and Granix® • Remove Neupogen® from formulary • Update PA criteria to reflect formulary changes. The committee had no comments or questions.	
	<u>Infectious Disease</u> • Oral Antibiotics (abbreviated) (P49-65 of Jan of 2017 P&T Packet) • Antiparasitics (P66-87 of Jan of 2017 P&T Packet)	Jenna Heath	10 Mins	The plan presented therapeutic review and recommendations for Infectious Disease medications with a focus on oral antibiotics and antiparasitics. Major recommendations included the following: **Oral Antibiotics:** <u>Formulary Recommendations</u>: • Add age maximum of 12 years to formulary oral solutions/suspensions and chewable tablet formulations. • Add quantity limit to formulary cefdinir, erythromycin and minocycline to ensure appropriate prescribing. • Remove the following from formulary:	**VOTES:** **<u>Oral Antibiotics</u>** 9 approved, 0 denied, 0 abstained *<u>Motion:</u>* Nicolas Jew **<u>Antiparasitics</u>** 9 approved, 0 denied, 0 abstained *<u>Motion:</u>* Nicolas Jew

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				demeclocycline, cefadroxil, cefditoren, ceftibuten, erythromycin base 250 mg tablet, PCE® (erythromycin base) • Add the following to formulary: amoxicillin 500 mg tablet, amoxicillin/clavulonate (Augmentin XR®) 1000-62.5 mg ER tablet, cefdinir • Update fill limit for azithromycin and clarithromycin to 1 fill per 60 days to prevent continuous use • Remove fill limit from linezolid to allow use for MDR TB PA Criteria Recommendations: • Update oral fluoroquinolone criteria based on formulary change for ciprofloxacin and levofloxacin solution • Update Xifaxan® criteria with the following: o Remove sulfamethoxazole-trimethoprim from criteria for traveler's diarrhea and to include levofloxacin as another formulary fluoroquinolone alternative o For IBS-D diagnosis, change requirement for preferred therapy from loperamide to at least one other product o Add criteria for non-formulary fluoroquinolones to require trial with formulary products Committee inquired what was the previous azithromycin fill limit. SFHP responded that it was 2 fills per 90 days and the reason for updating the fill limit to 1 fill per 60 days was to prevent continuous use of azithromycin. One example where chronic therapy with azithromycin is used inappropriately is long term therapy for Lyme disease. Committee also briefly discussed Tuberculosis eradication initiative. SFHP currently has all medications for multi drug resistant to be on formulary without restrictions with the exception of moxifloxacin and Sirturo® which require a prior authorization.	

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				Antiparasitics: Formulary Recommendations: • Change Albenza® (albendazole) quantity limit from #2 fills/year to #4 tablets/year. • Add Alinia® (nitazoxanide) 500mg tab, 100mg/5ml susp to formulary with quantity limit of #30/year • Add tinidazole 250, 500mg tablet to formulary with quantity limit of #30/year • Change Atovaquone/proguanil (Malarone®) quantity limits from #2 fills/year to #180 tabs/year • Add Daraprim® to formulary with prior authorization and include the compounded pyrimethamine plus leucovorin as a covered alternative to discuss with prescribing physician for toxoplasmosis. PA Criteria Recommendations: Topical Antiparasitics Criteria • Update criteria to reflect current formulary status of spinosad (Natroba®) as PA required. • Update criteria to allow approval of spinosad after trial and failure of first-line, formulary options and as an option for second-line therapy before using third-line, non-formulary options. • Spinosad is recommended treatment for lice where local resistance may occur while topical ivermectin is considered a treatment alternative. • Remove Lindane shampoo from criteria as American Academy of Pediatrics (AAP) does not recommend for the treatment of lice or scabies, even as second-line therapy. • Create new criteria for Nebupent® and Daraprim®. Committee inquired why the new quantity limit for Albenza® is 4 tablets year rather than 5-6 tablets which is the maximum dose seen in utilization data. SFHP responded that usual dosing for Albenza® is 4 tablets and anything above that amount needs to be evaluated for medical necessity. SFHP will research further indications where higher quantities may be needed.	

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				Committee also raised concern about the need for re-treatment with Albenza® and inquired how long it would take to approve an urgent PA request. SFHP responded that urgent requests have a 24 hour turn-around time.	
	Nutrition/Electrolytes • Enteral Nutrition Products (abbreviated) (P88-96 of Jan of 2017 P&T Packet) • Electrolytes, Vitamins, and Minerals (abbreviated) (P97-108 of Jan of 2017 P&T Packet) • Phosphate Binders (P109-117 of Jan of 2017 P&T Packet) • Potassium Depleters (P118-123 of Jan of 2017 P&T Packet)	Olga Mostovetsky	18 Mins	The plan presented therapeutic review and recommendations for Nutrition & Electrolyte medications. Major recommendations are listed below. **Enteral Nutrition Products:** Formulary Recommendations: (applies to Medi-Cal and Medicare/Medi-Cal only) • Remove all PA required products without utilization from formulary except PKU products • Add highly utilized non-formulary products to formulary with prior authorization PA Criteria Recommendations: For enteral nutrition product criteria, add requirement of dietary adjustment in addition to medical diagnosis and nutritional risk; cancer diagnoses do not require dietary adjustment. The committee had no comments or questions. **Electrolytes, Vitamins, and Minerals:** • Add low-cost utilized products to formulary without restrictions • Remove high cost products with formulary alternatives from formulary with grandfathering where appropriate • Remove non-utilized products from formulary The committee had no comments or questions. **Phosphate Binders:** • Add Renvela® powder packets to formulary with prior authorization for calcium acetate and Renvela® tablets • Add Velphoro® and Auryxia® to formulary with prior authorization requirement for calcium acetate The committee had no comments or questions. **Potassium Depleters:**	**VOTES:** **Enteral Nutrition Products (abbreviated):** 9 approved, 0 denied, 0 abstained *Motion:* Lisa Ghotbi **Electrolytes, Vitamins, and Minerals:** 9 approved, 0 denied, 0 abstained *Motion:* Ted Li **Phosphate Binders:** 9 approved, 0 denied, 0 abstained *Motion:* Nicolas Jew **Potassium Depleters:** 9 approved, 0 denied, 0 abstained *Motion:* Ron Ruggiero

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				• Add Veltassa® to formulary without restrictions • Add SPS oral powder (Kayexalate®, Kionex®) to formulary without restrictions The committee had no comments or questions.	
	OBGYN • Hormone Replacement Therapy (P124-136 of Jan of 2017 P&T Packet)	Jenna Heath	5 Mins	SFHP presented therapeutic review and recommendations for Hormone Replacement Therapy (HRT) medications. Major recommendations included adding Estrogel® to formulary and removing several non-utilized products from formulary (e.g. Femring®, estropipate tablet, norethindrone acetate-ethyl estradiol tablet, estradiol/norethindrone acetate tablet, Menest®.) SFHP pointed out that there may be some inappropriate use of these products in SFHP population as there are members over the age of 60 on HRT as well as members using HRT over a 5 year period. Committee asked whether HRT products are commonly used to treat transgender females. SFHP responded that use in GID is likely; however, because there are no gender restrictions on HRT products, it is difficult to say how common this use is. Committee also commented that Premarin vaginal cream can be misused. It can be used long-term for gender identity disorder but should be limited to short-term use for menopause.	**VOTES:** **HRT:** 9 approved, 0 denied, 0 abstained *Motion:* Ron Ruggiero
	Oncology (abbreviated) • Antineoplastics (P137-145 of January 2017 P&T Packet)	Jenna Heath	5 Mins	The plan presented therapeutic review and recommendations for Oncology medications. Formulary recommendations included adding all non-formulary oral tablet and capsule formulations to formulary with prior authorization. PA criteria recommendations included retiring all drug specific criteria and using blanket criteria for oncology medications. Blanket criteria were updated to require NCCN category 2b or greater evidence rating as well as genetic testing results and labs where indicated per package insert. The committee had no comments or questions.	**VOTES:** **Oncology (abbreviated): Antineoplastic:** 9 approved, 0 denied, 0 abstained *Motion:* Ron Ruggiero

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	Pain • Skeletal Muscle Relaxants (P146-150 of January 2017 P&T Packet) • NSAIDs and COX-2 inhibitors (P151-162 of January 2017 P&T Packet)	Jenna Heath	10 Mins	The plan presented therapeutic review and recommendations for skeletal muscle relaxants and NSAID medications. Major recommendations are listed below: **Skeletal Muscle Relaxants:** Formulary recommendations were to remove carisoprodol 350 mg tablets from formulary due to potential for psychological and physical dependence with grandfathering for current utilizers and to add a quantity limit of #120/30 days to methocarbamol due to abuse potential. Committee commented that there is low use of carisoprodol which is a positive finding. Committee also inquired whether it is possible to do outreach to providers prescribing muscle relaxants in combination with opioids and BZDs. SFHP responded that it plans this type of intervention at some point in the future. Committee also inquired what the look-back period will be for carisoprodol grandfathering. SFHP responded that usual look-back period is 6 months and committee requested that the look back period for carisoprodol should be 90 days instead. **NSAIDs and COX-2:** Major formulary recommendations included the following: • Add celecoxib and diclofenac 100 mg ER tablet to formulary • Add ketorolac to formulary with a quantity limit of 5 tablets per year • Add age limit, maximum of 12 years, to indomethacin and naproxen liquids Committee asked for clarification on the cost of celecoxib as it appears high in utilization table. SFHP responded that the cost was higher earlier in the year but dropped recently to the level where it is comparable to formulary NSAIDs.	**Skeletal Muscle Relaxants** 9 approved, 0 denied, 0 abstained *Motion:* Shawn Houghtaling, **NSAIDs and COX-2** 9 approved, 0 denied, 0 abstained *Motion:* Lisa Ghotbi

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	Pulmonary • Asthma/COPD (P163-184 of January 2017 P&T Packet) • Respiratory Devices (P185-187 of January 2017 P&T Packet) • Cystic Fibrosis (P188-205 of January 2017 P&T Packet)		15 Mins	The plan presented therapeutic review and recommendations for pulmonary medication classes. Major recommendations were as follows: **Asthma/COPD:** Formulary Recommendations: • Add Proair HFA® to formulary with quantity limit • Remove quantity limit from montelukast tablets and chewable tablets • Remove albuterol ER tablets from formulary due to lack of utilization • Add Advair Diskus to formulary with quantity limit of #60 per 30 days PA Criteria Recommendations: • New criteria proposed for Daliresp® based on GOLD guideline placement. Committee requested that SFHP provide a status update on Advair Diskus® generic launch a the next meeting. **Respiratory Devices:** No changes were proposed to formulary placement of respiratory supply products. The committee had no comments or questions on current formulary placement or utilization. **Cystic Fibrosis:** Formulary Recommendations: • Add Orkambi® (lumacaftor/ivacaftor) to formulary with PA due to unique indication (F508del mutation) • Add acetylcysteine 200 mg/ml vial to formulary without restrictions to align with 100 mg/ml vial PA Criteria Recommendations: • Place tobramycin PAK (KITABISTM PAK) on same level as tobramycin (TOBI®) due to generic availability • Add non-cystic fibrosis bronchiectasis diagnosis to tobramycin criteria The committee had no comments or questions.	**Asthma/ COPD:** 9 approved, 0 denied, 0 abstained *Motion:* Nicolas Jew **Respiratory Devices** 9 approved, 0 denied, 0 abstained *Motion:* Lisa Ghotbi **Cystic Fibrosis** 9 approved, 0 denied, 0 abstained *Motion:* Lisa Ghotbi

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	Basaglar (P206-213 of January 2017 P&T Packet)	Jenna Heath	5 Mins	SFHP discussed recently marketed follow on biologic for Lantus®, Basaglar® (insulin glargine). Discussion focused on clinical equivalence and cost comparison between the two products. Formulary recommendation was to make Basaglar® the preferred insulin glargine product and to remove Lantus® vials and Lantus Solostar® from formulary. New users will be required to use Basaglar prior to filling Lantus®, while current users of Lantus® will be grandfathered at this time. SFHP will consider an active conversion of current utilizers of Lantus® to Basaglar® at a later date. SFHP has consulted with Dr. Elizabeth Murphy, Chief of the Endocrinology and Metabolism Division at SFGH, who agreed with this approach. The committee had no questions or concerns.	9 approved, 0 denied, 0 abstained *Motioned:* Joseph Pace
	Additional Proposed Changes to SFHP Formulary (P214-214 of January 2017 P&T Packet)	Olga Mostovetsky	2 Mins	The plan discussed miscellaneous proposed formulary changes which included removing quantity limits from desmopressin and adding Amitiza®, Linzess® and Movantik® to formulary with PA. The committee had no questions or concerns.	**VOTES:** **Annual Formulary review** 9 approved, 0 denied, 0 abstained *Motion:* Lisa Ghotbi
			******RECONVENE IN OPEN SESSION******		
6.	**Summary of Closed Session**	James Glauber	2 Mins	Reconvened Open session around 9:20am	*Non-voting*
7.	**Additional Proposed Changes to SFHP Prior Authorization Criteria** (P215-218 of January 2017 P&T Packet)	Olga Mostovetsky	10 Mins	SFHP presented changes to existing criteria for PPIs and agents for constipation. The committee had no questions or concerns.	**VOTES:** **Additional Proposed Changes to SFHP Prior Authorization Criteria** 9 approved, 0 denied, 0 abstained *Motion:* Shawn Houghtaling
8.	**Review and Approval of Interim Formulary Changes and Formulary Placement for New Drugs to Market** (P220-233 of January 2017 P&T Packet)		5 Mins	SFHP presented interim formulary changes and formulary status for new drugs to market. In the interest of time, clinical overview of new drugs was not discussed. The committee had no questions or comments.	**VOTES:** **Review and Approval of Interim Formulary Changes and Formulary Placement for New Drugs to Market** 9 approved, 0 denied, 0 abstained *Motion:* Shawn Houghtaling
9.	**Pharmacy Policy & Procedure Updates and Monitoring** (P234-261 January 2017 P&T Packet)	Olga Mostovetsky	5 Mins	The plan presented changes to the Pharmacy Policy and Procedures (P&P) listed below: • Pharm-01: Pharmacy & Therapeutic Committee	**VOTES:** **Pharmacy Policy and Procedure Updates** 9 approved, 0 denied, 0 abstained

	Topic	Brought By	Time/ Duration	Discussion	Action
				• Pharm-02: Pharmacy Prior Authorization • Pharm-07: Emergency Supply Policy • Pharm-08: Pharmacy Formulary, Prior Authorization Criteria, & Policy Annual Review • Pharm-13: After-Hours pharmacy Access Pharm-14: Formulary Exclusions, Limits, and Quotas Changes included language updates to meet NCQA accreditation standards and various regulatory requirements. In addition, Emergency Supply Policy (Pharm-07) was updated to include additional medication classes available for a point-of-sale emergency 5 day supply. These classes are opioid dependency medications, antidepressants and albuterol/levalbuterol products. SFHP clarified that the change to opioid dependency medications does not apply to Medi-Cal line of business as these medications are carved out for Medi-Cal. The committee had no questions or concerns.	*Motion:* Lisa Ghotbi
10.	**Action Items**	Olga Mostovetsky		Summarized action Items for next meeting to investigate and report.	**Action Items for next meeting (**April 2017 P&T Committee Meeting**):** • In PA criteria for Promacta® and Nplate®, for ITP indication clarify that only one prior therapy is required for approval. • Research indications for Albenza® which may require dosing greater than 4 tablets. • Design outreach to providers prescribing muscle relaxants in combination with opioids and BZDs. • Provide an update on generic launch of Advair Diskus®.
11.	**Follow up discussion from October 2016 P&T Committee Meeting** (P262-262 of October 2016 P&T Packet)	Olga Mostovetsky	5 Mins	The plan provided follow up items from October P&T Committee meeting. Trazodone utilization was requested to estimate proportion of members using trazodone for insomnia (doses of 50-100 mg per day) vs depression (doses of 150 mg per day and higher). Between 10/1/15-	*Non-Voting.*

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				9/30/16, there were 9,993 claims for 2,519 members across all trazodone strengths. 91% of prescriptions were for 50 and 100 mg strengths indicating that most members are using trazodone for insomnia.	
12.	**Adjournment**	James Glauber	2 Mins	The meeting adjourned at 9:35 am. 2017 P&T Committee Meeting dates are: • Wednesday, April 19, 2017 • Wednesday, July 19, 2017 • Wednesday, October 18, 2017	

The meeting was adjourned at 9:35 AM

Respectfully submitted by:

---------- January 27, 2017 P&T Committee Approved: on April 19, 2017

James Glauber, MD, MPH
Chief Medical Officer

Date: