Alabama Medicaid DUR Board Meeting Minutes
January 25, 2017

Members Present: Kelli Littlejohn Newman, Melinda Rowe, Dan McConaghy, Frank Pettyjohn, Bernie Olin, Paula Thompson, PJ Hughes

Also Present: Tiffany Minnifield, Lori Thomas, Clemice Hurst, Heather Vega, Kristin Marvin

Present via Conference Call: Kristian Testerman, Lauren Ward, Samir Hadid, Amy Donaldson, Michelle Stiles, Joshua Lee, Holley Rice, Elaine Alexander, Lisa Channell

Members Absent: Robert Moon, Christopher Randolph, Denyse Thornley-Brown, Donald Kern, Chris Phung, Marilyn Bulloch

Call to Order: The DUR meeting was called to order by F. Pettyjohn at approximately 1:04p.m.

Review and Adoption of Minutes: The minutes of the October 26, 2016 meeting were presented and P. Thompson made a motion to approve the minutes. B. Olin seconded the motion and the motion was approved unanimously.

Prior Authorization and Overrides Update: L. Thomas began the Prior Authorization and Overrides Update with the Monthly Manual Prior Authorizations and Overrides Report for the month of July 2016. She reported 9,180 total manual requests and 19,698 total electronic requests. From the Prior Authorization and Override Response Time Ratio report for July 2016, L. Thomas reported that approximately 80% of all manual PAs and 84% of all overrides were completed in less than two hours. Ninety-three percent of all manual PAs and 95% of all overrides were completed in less than four hours. Ninety-six percent of all manual PAs and 97% of all overrides were completed in less than eight hours. For the month of August 2016, L. Thomas reported 10,001 manual PA requests and 23,072 electronic PA requests were received. She reported that 72% of all manual PAs and 73% of all overrides were completed in less than two hours. Eighty-six percent of all manual PAs and 88% of all overrides were completed in less than four hours. Ninety-three percent of all manual PAs and all overrides were completed in less than eight hours. For the month of September 2016, L. Thomas reported 10,331 manual PA requests and 20,460 electronic PA requests. L. Thomas reported that approximately 73% of all manual PAs and 72% of all overrides were completed in less than two hours. Eighty-eight percent of all manual PA requests and all overrides were completed in less than four hours. Ninety-four percent of all manual PA requests and all overrides were completed in less than eight hours.

Program Summary Review: L.Thomas briefly reviewed the Alabama Medicaid Program Summary for the months of January 2016 through June 2016. She reported 3,264,497 total prescriptions, 202,686 average recipients per month using pharmacy benefits, and an average paid per prescription of $101.24.

Cost Management Analysis: L.Thomas reported an average cost per claim of $97.55 for September 2016 and emphasized that the table contained the average cost per claim over the past two years. From the 3rd Quarter 2016 Drug Analysis, L.Thomas reported 79.1% generic utilization, 9.4% brand single-source, 7.7% brand multi-source (those requests which required a DAW override), and 4% OTC and "other". From the Top 25 Drugs Based on Number of Claims from 07/01/2016 – 09/30/2016, L.Thomas reported the top five drugs: amoxicillin, hydrocodone-acetaminophen, cetirizine, ProAir® HFA, and montelukast. L. Thomas then reported the top five drugs from the Top 25 Drugs Based on Claims Cost from 07/01/16 – 09/30/2016: Vyvanse®, Focalin XR®, Invega® Sustenna®, ProAir® HFA, and Lyrica®. L. Thomas reminded the Board that Vyvanse® and Focalin XR® are preferred agents. From the Top 15 Therapeutic Classes by Total Cost of Claims for the same time frame, L.Thomas reported the top five classes: Antipsychotic Agents, Amphetamines, Miscellaneous Anticonvulsants, Respiratory and CNS Stimulants, and Insulins.

Review of CMS Annual Report – Buprenorphine: L. Thomas provided data from the 2015 Fiscal Year CMS Annual Report which focused on the utilization of buprenorphine products. L. Thomas began the discussion by pointing out that Suboxone SL Film was the 2nd most requested drug by number of prior authorizations. Buprenorphine SL tablets were the 6th most requested drug by number of prior authorizations. F. Pettyjohn asked what the CMS Annual Report was comprised of. K. Newman replied that is a compilation of state data that can be used for comparative purposes. The data consists of RDUR interventions, drug/drug class specific data (antipsychotics, buprenorphine, methadone), and most recently prior authorization data. L. Thomas stated that the most recent CMS Annual Report had more questions related to prior authorizations than in previous years. L. Thomas reviewed the questions related to buprenorphine and buprenorphine/naloxone combinations that were found in the CMS Annual Report. K. Newman indicated that she anticipates CMS will release guidance on buprenorphine products once the data from each state is reviewed. M. Rowe briefly discussed policy that the Alabama Board of Medical Examiners released regarding risk and abuse mitigation strategies by prescribing physicians.

Review of Opioid Dependence Treatment Patient Consent Form: C. Hurst began the Informed Consent form discussion by letting the Board know that the Agency strives to keep patient documents on a 7th grade level or below. The document included in the DUR Pack was a draft form covering the main topics and was open for Board review and input. C. Hurst indicated the patients would fill out the consent form, the physician would sign the form, and the form would be sent in with PA requests. L. Thomas added that the Academic Detailers could go over the form with prescribers and let the prescribers know the form must be attached to the PA form when submitted for review. After Board review and input, K. Newman asked the Board for a recommendation and vote. P.J. Hughes recommended the Board approve the form as amended. D. McConaghy seconded the motion and the motion was approved unanimously.

RDUR Intervention Report: L. Thomas presented the RDUR Activity Report for July 2016. She reported 645 profiles reviewed and 559 letters sent with 99 responses received as of the date of the report. She reported 44 of 80 physicians indicated that they found the RDUR letters "useful" or "extremely useful". The criteria for the cycle of intervention letters included Therapeutic Appropriateness (use of narcotics/opioids and sickle cell disease); Drug-Drug Interactions (methadone Black Box Warning; QT prolongation); Drug-Drug Interactions (additive CNS effects – methadone and CNS depressants); Drug-Drug Interactions (trazodone and carbamazepine; trazodone and moderate-strong CYP3A4 inhibitors); Hepatitis C SVR Response Rates; and Appropriate Use (concurrent use of buprenorphine and pure opiate agonists). L. Thomas then presented the RDUR Activity Report for August 2016. She reported 744 profiles reviewed and 901 letters sent with 134 responses received as of the date of the report. She reported 88 of 115 physicians indicated that they found the RDUR letters "useful" or "extremely useful". The criteria for the cycle of intervention letters included Drug-Disease Precaution (NSAIDs and hepatic impairment); Drug-Drug Interaction (NSAIDs and loop diuretics); Therapeutic Duplication of NSAIDs; Hepatitis C SVR Response Rates; Appropriate Use (concurrent use of buprenorphine and pure opiate agonists). The September 2016 Activity Report indicated 674 profiles reviewed and 613 letters sent with 152 responses received as of the date of the report. L. Thomas reported 66 of 107 physicians indicated that they found the RDUR letters "useful" or "extremely useful". The criteria for the cycle of intervention letters were Drug-Drug Interaction (tramadol and opioid analgesics); Drug-Disease Precaution (risk of fractures: narcotics/opioids and osteoporosis; benzodiazepines/sedatives/hypnotics and osteoporosis); Therapeutic Appropriateness (narcotics/opioids and sickle cell disease); Drug-Drug Interaction (ADHD stimulants and narcotics/opioids); Hepatitis C SVR Response Rates; Appropriate Use (concurrent use of buprenorphine and pure opiate agonists).

Proposed Criteria: L.Thomas presented the proposed set of 45 criteria to the Board. T.Minnifield instructed the Board members to mark their ballots. Of the 45 criteria, results from the criteria vote returned 45 approved.

Medicaid Update: T. Minnifield reminded the Board members that all updated Medicaid drug lists provided are also available online. T. Minnifield informed the Board that F. Pettyjohn will be stepping down from Board duties and T. Minnifield presented him with a certificate of appreciation.

New Business: K. Newman told the Board that the Regional Care Organizations (RCOs) should be implemented October 1, 2017. She also mentioned that the next legislative session begins on February 7, 2017.

P & T Committee Update: C. Hurst began the P & T Update by informing the Board that the last meeting was held on November 9, 2016, and covered the first part of the anti-infectives and new drug reviews for Praluent®, Epclusa®, and Viekira XR™. The next P & T meeting is scheduled for February 8, 2017, at 9 a.m. and will cover the remaining anti-infectives and new drug reviews for Xeljanz® and Entresto™. C. Hurst also mentioned that the next ALERT would have information pertaining to the Hepatitis C Agents Patient Consent Form and the Opioid Dependence Treatment Patient Consent Form.

Next Meeting Date: F. Pettyjohn notified the Board that the next DUR meeting will be held on April 26, 2017. A motion to adjourn the meeting was made by P. Thompson. B. Olin seconded the motion and the meeting was adjourned at 2:16 p.m.

Respectfully submitted,

Lori Thomas, PharmD

Lori Thomas, Pharm

ALABAMA MEDICAID
RETROSPECTIVE DRUG UTILIZATION REVIEW
CRITERIA RECOMMENDATIONS

Criteria Recommendations	*Accepted*	*Approved As Amended*	*Rejected*

1. Indacaterol/Glycopyrrolate / Overutilization ____√____ _____ _____

Alert Message: The manufacturer's recommended maximum daily dose of Utibron Neohaler (indacaterol/glycopyrrolate) is one inhalation twice daily. Excessive use of an indacaterol-containing agent, or use in conjunction with other medications containing a beta-2-agonist, can result in clinically significant cardiovascular effects and may be fatal.

Conflict Code: ER - Overutilization
Drugs/Diseases

Util A	Util B	Util C
Indacaterol/Glycopyrrolate		

Max Dose: 2 capsules/day (55mcg indacaterol/31.2 mcg glycopyrrolate)

References:
Utibron Neohaler Prescribing Information, Oct. 2015, Novartis Pharmaceuticals Corp.
Clinical Pharmacology, 2016 Elsevier/Gold Standard.

2. Indacaterol/Glycopyrrolate / Adrenergic Drugs ____√____ _____ _____

Alert Message: Caution should be exercised when Utibron Neohaler (indacaterol/glycopyrrolate) is prescribed concurrently with other adrenergic sympathomimetic agents, administered by any route, because the sympathetic effects of the indacaterol component of the combination product may be potentiated.

Conflict Code: DD- Drug/Drug Interaction
Drugs/Diseases

Util A	Util B		
Indacaterol/Glycopyrrolate	Ephedrine	Diethylpropion	Oxymetazoline
Metaproterenol	Lisdexamfetamine	Tetrahydrozoline	
	Epinephrine	Terbutaline	Benzphetamine
	Pseudoephedrine	Methamphetamine	Phentermine
	Phenylephrine	Methylphenidate	Phendimetrazine
	Albuterol	Amphetamine	Naphazoline
	Pirbuterol	Dextroamphetamine	

References:
Utibron Neohaler Prescribing Information, Oct. 2015, Novartis Pharmaceuticals Corp.
Clinical Pharmacology, 2016 Elsevier/Gold Standard.

Criteria Recommendations	*Accepted*	*Approved As Amended*	*Rejected*

3. Indacaterol/Glycopyrrolate / Xanthine Derivatives & Steroids ____√____ _____ _____

Alert Message: Caution should be exercised when Utibron Neohaler (indacaterol/glycopyrrolate) is prescribed concurrently with xanthine derivatives, steroids, or diuretics because concomitant administration may potentiate the hypokalemic effect of the indacaterol component of the combination agent. The ECG changes or hypokalemia that may result from the administration of non-potassium sparing diuretics can be acutely worsened by beta-agonists.

Conflict Code: DD - Drug/Drug Interaction
Drugs/Diseases

Util A	Util B	Util C
Indacaterol/Glycopyrrolate	Theophylline	
	Aminophylline	
	Dyphylline	
	Betamethasone	
	Budesonide	

Cortisone
Dexamethasone
Hydrocortisone
Methylprednisolone
Prednisolone
Prednisone

References:
Utibron Neohaler Prescribing Information, Oct. 2015, Novartis Pharmaceuticals Corp.
Clinical Pharmacology, 2016 Elsevier/Gold Standard.

4. Indacaterol/Glycopyrrolate / Non-Potassium Sparing Diuretics ____√____ _____ _____

Alert Message: Caution should be exercised when Utibron Neohaler (indacaterol/glycopyrrolate) is prescribed concurrently with non-potassium sparing diuretics because concomitant administration may potentiate the ECG changes or hypokalemia that may result from the administration of the diuretic.

Conflict Code: DD - Drug/Drug Interaction
Drugs/Diseases

Util A	Util B	Util C
Indacaterol/Glycopyrrolate	Chlorothiazide	
	Chlorthalidone	
	HCTZ	
	Indapamide	
	Methyclothiazide	

Metolazone
Furosemide
Bumetanide
Torsemide

References:
Utibron Neohaler Prescribing Information, Oct. 2015, Novartis Pharmaceuticals Corp.
Clinical Pharmacology, 2016 Elsevier/Gold Standard.

Criteria Recommendations	*Accepted*	*Approved As Amended*	*Rejected*

5. Indacaterol/Glycopyrrolate / Nonselective Beta Blockers ____√____ _____ _____

Alert Message: Concurrent use of Utibron Neohaler (indacaterol/glycopyrrolate) with a beta-adrenergic receptor antagonist may result in mutual antagonism. Beta-blockers not only block the therapeutic effects of beta-agonists, but may produce severe bronchospasm in patients with asthma and COPD. If concomitant therapy cannot be avoided, consider a cardioselective beta-blocker administered with caution.

Conflict Code: DD - Drug/Drug Interaction
Drugs/Diseases

Util A	Util B	Util C **(Negating)**
Indacaterol/glycopyrrolate	Carvedilol	Acebutolol
Nadolol	Atenolol	
Labetalol	Betaxolol	
	Penbutolol	Bisoprolol
	Pindolol	Metoprolol
	Propranolol	Nebivolol
	Sotalol	
	Timolol	

References:
Utibron Neohaler Prescribing Information, Oct. 2015, Novartis Pharmaceuticals Corp.
Clinical Pharmacology, 2016 Elsevier/Gold Standard.

6. Indacaterol/Glycopyrrolate / Cardiovascular, Convulsive Disorders, Thyrotoxicosis & Diabetes ____√____ _____ _____

Alert Message: Utibron Neohaler (indacaterol/glycopyrrolate) should be used with caution in patients with cardiovascular or convulsive disorders, thyrotoxicosis, diabetes, or sensitivity to sympathomimetic drugs. Indacaterol is a sympathomimetic amine and can aggravate these conditions.

Conflict Code: MC - Drug (Actual) Disease Precaution
Drugs/Diseases

Util A	Util B	Util C
Indacaterol/glycopyrrolate	Arrhythmia	
	Hypertension	
	Heart Failure	
	Epilepsy	
	Diabetes	

References:
Utibron Neohaler Prescribing Information, Oct. 2015, Novartis Pharmaceuticals Corp.
Clinical Pharmacology, 2016 Elsevier/Gold Standard.

7. Indacaterol/Glycopyrrolate / MAOIs, TCAs & QT Prolongation Agents ____√____ _____ _____

Alert Message: Utibron Neohaler (indacaterol/glycopyrrolate) should be administered with extreme caution to patients being treated with MAOIs, TCAs, or drugs known to prolong the QTc interval because the action of the adrenergic agonist component, indacaterol, on the cardiovascular system may be potentiated by these agents.

Conflict Code: DD - Drug/Drug Interaction
Drugs/Diseases

Util A	Util B				
Indacaterol/ Glycopyrrolate	Albuterol	Disopyramide	Imipramine	Pazopanib	Sotalol
	Alfuzosin	Dofetilide	Indapamide	Pentamidine	Tizanidine
Amantadine	Dolasetron	Isradipine	Pimozide	Tolterodine	
Amiodarone	Doxepin	Itraconazole	Posaconazole	Trazodone	
Amitriptyline	Dronedarone	Ketoconazole	Procainamide	TMP/SMZ	
Amphetamine	Droperidol	Lapatinib	Propafenone	Trimipramine	
Arsenic Trioxide	Ephedrine	Levalbuterol	Protriptyline	Vandetanib	
Asenapine	Epinephrine	Levofloxacin	Quetiapine	Vardenafil	
Atazanavir	Erythromycin	Lithium	Quinidine	Venlafaxine	
Atomoxetine	Escitalopram	Metaproterenol	Ranolazine	Ziprasidone	
Azithromycin	Felbamate	Methadone	Risperidone	Zolmitriptan	
Chloral Hydrate	Flecainide	Moexipril/HCTZ	Ritonavir	Ezogabine	
Chloroquine	Fluconazole	Moxifloxacin	Salmeterol	Rasagiline	
Chlorpromazine	Fluoxetine	Nicardipine	Saquinavir	Phenelzine	
Ciprofloxacin	Foscarnet	Nilotinib	Sertraline	Thioridazine	Tranylcypromine
Citalopram	Fosphenytoin	Norfloxacin	Solifenacin	Clarithromycin	Galantamine
Nortriptyline	Linezolid				
Clomipramine	Gemifloxacin	Octreotide	Sunitinib		
Clozapine	Granisetron	Ofloxacin	Tacrolimus		
Dasatinib	Haloperidol	Ondansetron	Tamoxifen		
Desipramine	Isocarboxazid	Paliperidone	Telithromycin		
Diphenhydramine	Iloperidone	Paroxetine	Terbutaline		

References:
Utibron Neohaler Prescribing Information, Oct. 2015, Novartis Pharmaceuticals Corp.
Clinical Pharmacology, 2016 Elsevier/Gold Standard.

8. Indacaterol/Glycopyrrolate / Therapeutic Appropriateness ____√____ _____ _____

Alert Message: The safety and effectiveness of Utibron Neohaler (indacaterol/glycopyrrolate) have not been established in children.

Conflict Code: TA - Therapeutic Appropriateness
Drugs/Diseases

Util A	Util B	Util C
Indacaterol/Glycopyrrolate		

Age Range: 0-18 yoa

References:
Utibron Neohaler Prescribing Information, Oct. 2015, Novartis Pharmaceuticals Corp.
Clinical Pharmacology, 2016 Elsevier/Gold Standard.

Criteria Recommendations	*Accepted*	*Approved As Amended*	*Rejected*

9. Indacaterol/Glycopyrrolate / Therapeutic Appropriateness ____√____ _____ _____

Alert Message: Utibron Neohaler (indacaterol/glycopyrrolate) contains a long-acting beta-2-adrenergic agonist (LABA) and all LABAs increase the risk of asthma-related death. The safety and efficacy of the indacaterol component in patients with asthma have not been established. Indacaterol/glycopyrrolate is not indicated for the treatment of asthma.

Conflict Code: TA - Therapeutic Appropriateness **(Black Box Warning)**
Drugs/Diseases

Util A	Util B	Util C **(Include)**
Indacaterol/Glycopyrrolate		Asthma

References:
Utibron Neohaler Prescribing Information, Oct. 2015, Novartis Pharmaceuticals Corp.
Clinical Pharmacology, 2016 Elsevier/Gold Standard.

10. Indacaterol/Glycopyrrolate / Non-adherence ____√____ _____ _____

Alert Message: Based on refill history, your patient may be under-utilizing Utibron Neohaler (indacaterol/glycopyrrolate). Non-adherence to the prescribed dosing regimen may result in sub-therapeutic effects, which may lead to decreased outcomes and additional healthcare costs.

Conflict Code: LR - Nonadherence
Drugs/Diseases

Util A	Util B	Util C
Indacaterol/Glycopyrrolate		

References:
van Boven JF, Chavannes NH, van der Molen T, et al. Clinical and Economic Impact of Non-adherence in COPD: A Systematic Review. Respir Med. 2015 Jan;108(1):103-113.
Restrepo RD, Alvarez MT, Wittnebel LD, et al., Medication Adherence Issues in Patients Treated for COPD. International Journal of COPD. 2008;3(3):371-384.
Simoni-Wastila L, Wei Y, Qian J, et al., Association of Chronic Obstructive Pulmonary Disease Maintenance Medication Adherence With All-Cause Hospitalization and Spending in a Medicare Population. Am Jrnl Geriatr Pharmacother. 2012 Jun;10(3):201-210.
Lareau SC, Yawn BP. Improving Adherence with Inhaler Therapy in COPD. International Journal COPD. 2010 Nov 24;5:401-406.

Criteria Recommendations	*Accepted*	*Approved As Amended*	*Rejected*

11. Glycopyrrolate / Overutilization ____√____ _____ _____

Alert Message: The manufacturer's recommended maximum daily dose of Seebri Neohaler (glycopyrrolate) is one inhalation twice daily. More frequent administration or greater number of inhalations (more than 1 capsule twice daily) is not recommended.

Conflict Code: ER - Overutilization
Drugs/Diseases

Util A	Util B	Util C
Glycopyrrolate		

Max Dose: 2 capsules/day (31.2 mcg glycopyrrolate)

References:
Seebri Neohaler Prescribing Information, Oct. 2015, Novartis Pharmaceuticals Corp.
Clinical Pharmacology, 2016 Elsevier/Gold Standard.

12. Glycopyrrolate - All Inhalation / Anticholinergic Agents ____√____ _____ _____

Alert Message: The concurrent use of a glycopyrrolate-containing agent (Utibron Neohaler & Seebri Neohaler) with other anticholinergic agents should be avoided. Glycopyrrolate is an anticholinergic agent and concomitant use with other anticholinergics may lead to an increase in anticholinergic adverse effects.

Conflict Code: DD - Drug/Drug Interaction
Drugs/Diseases

Util A	Util B			Util C
Indacaterol/Glycopyrrolate	Trihexyphenidyl	Trospium	Cyclizine	Oxybutynin
Glycopyrrolate	Benztropine	Hyoscyamine	Dicyclomine	Trimethobenzamide
	Orphenadrine	Scopolamine	Diphenhydramine	Flavoxate
	Darifenacin	Propantheline	Meclizine	Metscopolamine
	Fesoterodine	Mepenzolate	Solifenacin	Tolterodine

References:
Seebri Neohaler Prescribing Information, Oct. 2015, Novartis Pharmaceuticals Corp.
Utibron Neohaler Prescribing Information, Oct. 2015, Novartis Pharmaceuticals Corp.
Clinical Pharmacology, 2016 Elsevier/Gold Standard.

Criteria Recommendations	*Accepted*	*Approved As Amended*	*Rejected*

13. Glycopyrrolate / Non-adherence ____√____ _____ _____

Alert Message: Based on refill history, your patient may be under-utilizing Seebri Neohaler (glycopyrrolate). Non-adherence to the prescribed dosing regimen may result in sub-therapeutic effects, which may lead to decreased outcomes and additional healthcare costs.

Conflict Code: LR - Nonadherence
Drugs/Diseases

Util A	Util B	Util C
Glycopyrrolate		

References:

van Boven JF, Chavannes NH, van der Molen T, et al. Clinical and Economic Impact of Non-adherence in COPD: A Systematic Review. Respir Med. 2015 Jan;108(1):103-113.
Restrepo RD, Alvarez MT, Wittnebel LD, et al., Medication Adherence Issues in Patients Treated for COPD. International Journal of COPD. 2008;3(3):371-384.
Simoni-Wastila L, Wei Y, Qian J, et al., Association of Chronic Obstructive Pulmonary Disease Maintenance Medication Adherence With All-Cause Hospitalization and Spending in a Medicare Population. Am Jrnl Geriatr Pharmacother. 2012 Jun;10(3):201-210.
Lareau SC, Yawn BP. Improving Adherence with Inhaler Therapy in COPD. International Journal COPD. 2010 Nov 24;5:401-406.

14. Glycopyrrolate / Narrow Angle Glaucoma ____√____ _____ _____

Alert Message: Seebri Neohaler (glycopyrrolate) should be used with caution in patients with narrow-angle glaucoma. Glycopyrrolate is an anticholinergic agent and its use in this patient population can worsen the condition.

Conflict Code: TA – Therapeutic Appropriateness
Drugs/Diseases

Util A	Util B	Util C **(Include)**
Glycopyrrolate		Narrow Angle Glaucoma

References:

Seebri Neohaler Prescribing Information, Oct. 2015, Novartis Pharmaceuticals Corp.
Clinical Pharmacology, 2016 Elsevier/Gold Standard.

Criteria Recommendations	*Accepted*	*Approved As Amended*	*Rejected*

15. Glycopyrrolate / Urinary Ret./Prost Hyperplasia/Bladder Neck Obst. ____√____ _____ _____

Alert Message: Seebri Neohaler (glycopyrrolate) should be used with caution in patients with urinary retention. Glycopyrrolate is an anticholinergic agent and its use can worsen urinary retention, especially in patients with prostatic hyperplasia or bladder neck obstruction.

Conflict Code: TA – Therapeutic Appropriateness
Drugs/Diseases

Util A	Util B	Util C **(Include)**
Glycopyrrolate		Urinary Retention
		Prostatic Hyperplasia
		Bladder neck Obstruction

References:
Seebri Neohaler Prescribing Information, Oct. 2015, Novartis Pharmaceuticals Corp.
Clinical Pharmacology, 2016 Elsevier/Gold Standard.

16. Glycopyrrolate / Severe Renal Impairment ____√____ _____ _____

Alert Message: Renal impairment has an impact on the systemic exposure to Seebri Neohaler (glycopyrrolate). In patients with severe renal impairment (estimated GFR < 30 mL/min/1.73m^2), including those with end-stage renal disease (ESRD) requiring dialysis, glycopyrrolate should only be used if the expected benefit outweighs the potential risk due to potential risk of increased systemic exposure.

Conflict Code: TA – Therapeutic Appropriateness
Drugs/Diseases

Util A	Util B	Util C **(Include)**
Glycopyrrolate		CKD 4 & 5
		ESRD
		Dialysis

References:
Seebri Neohaler Prescribing Information, Oct. 2015, Novartis Pharmaceuticals Corp.
Clinical Pharmacology, 2016 Elsevier/Gold Standard.

17. Mepolizumab / Overutilization ____√____ _____ _____

Alert Message: The manufacturer's recommended dose of Nucala (mepolizumab) is 100 mg administered once every 4 weeks by subcutaneous injection.

Conflict Code: ER - Overutilization
Drugs/Diseases

Util A	Util B	Util C
Mepolizumab		

Max Dose: 1 injection/4 weeks

References:
Nucala Prescribing Information, Nov. 2015, GlaxoSmithKline.
Clinical Pharmacology, 2016 Elsevier/Gold Standard.

Criteria Recommendations	*Accepted*	*Approved As Amended*	*Rejected*

18. Mepolizumab / Overutilization ___√___ _____ _____

Alert Message: The safety and efficacy of Nucala (mepolizumab) in pediatric patients younger than 12 years of age have not been established.

Conflict Code: TA – Therapeutic Appropriateness
Drugs/Diseases

Util A	Util B	Util C
Mepolizumab		

Age Range: 0-11yoa

References:
Nucala Prescribing Information, Nov. 2015, GlaxoSmithKline.
Clinical Pharmacology, 2016 Elsevier/Gold Standard.

19. Mepolizumab / Helminth Infection ___√___ _____ _____

Alert Message: The patient has a diagnosis of a helminth infection and is receiving Nucala (mepolizumab) which may adversely influence a patient's response against parasitic infections. Treat patients with pre-existing helminth infections before initiating therapy with mepolizumab. If patients become infected while receiving treatment with mepolizumab and do not respond to anti-helminth treatment, discontinue mepolizumab treatment until infection resolves. Mepolizumab is an interleukin-5 antagonist (IL-5) which reduces the production and survival of eosinophils.

Conflict Code: MC – Drug (Actual) Disease Precaution
Drugs/Diseases

Util A	Util B	Util C
Mepolizumab	Helminth Infection	

References:
Nucala Prescribing Information, Nov. 2015, GlaxoSmithKline.
Clinical Pharmacology, 2016 Elsevier/Gold Standard.

Criteria Recommendations	*Accepted*	*Approved As Amended*	*Rejected*

20. Genvoya / Nonadherence ____√____ _____ _____

Alert Message: Based on refill history, your patient may be under-utilizing Genvoya (EVG/c/FTC/TAF). Non-adherence to the prescribed dosing regimen may result in insufficient plasma levels of the agents in the combination product and therefore only partial suppression of viral load leading to the development of resistance, HIV progression, and increased mortality.

Conflict Code: LR - Nonadherence
Drugs/Diseases

Util A	Util B	Util C
EVG/c/FTC/TAF		

References:

Genvoya Prescribing Information, November 2015, Gilead Sciences, Inc.
Hoffman C, Mulcahy F, Goals and Principles of Therapy - Eradication, Cost, Prevention and Adherence. Hoffman C, Rockstroh J, Kamps BS, eds. HIV Medicine, Flying Publishers-Paris, Cagliari, Wuppertal, Sevilla, 2005:167-173.
Panel on Antiretroviral Guidelines for Adults and Adolescents. Guidelines for the Use of Antiretroviral Agents in HIV-1 Infected Adults and Adolescents. Department of Health and Human Services. April 9, 2015. Available at: http://www.aidsinfo.nih.gov/ContentFiles/AdultandAdolescentGL.pdf.

21. Genvoya / Overutilization ____√____ _____ _____

Alert Message: Genvoya (EVG/c/FTC/TAF) may be over-utilized. The manufacturer's maximum recommended dose of the combination agent in adults and pediatric patients 12 years and older with body weight of at least 35 kg, is one (1) tablet orally once daily with food.

Conflict Code: ER - Overutilization
Drugs/Diseases

Util A	Util B	Util C
EVG/c/FTC/TAF		

Max Dose: 1 tablet/day

References:

Genvoya Prescribing Information, November 2015, Gilead Sciences, Inc.
Clinical Pharmacology, 2015 Elsevier/Gold Standard.

Criteria Recommendations	*Accepted*	*Approved As Amended*	*Rejected*

22. Genvoya / Severe Renal Disease ____√____ _____ _____

Alert Message: Genvoya (EVG/c/FTC/TAF) use is not recommended in patients with estimated creatinine clearance below 30 ml per minute as the safety of EVG/c/FTC/TAF has not been established in these patients.

Conflict Code: TA – Therapeutic Appropriateness
Drugs/Diseases

Util A	Util B	Util C **(Include)**
EVG/c/FTC/TAF		CKD Stage 4 & 5

Max Dose: 1 tablet per day

References:
Genvoya Prescribing Information, November 2015, Gilead Sciences, Inc.
Clinical Pharmacology, 2015 Elsevier/Gold Standard.

23. Genvoya / Severe Hepatic Impairment ____√____ _____ _____

Alert Message: Genvoya (EVG/c/FTC/TAF) use is not recommended in patients with severe hepatic impairment as there is not pharmacokinetic or safety data available regarding the use of EVG/c/FTC/TAF in these patients.

Conflict Code: TA – Therapeutic Appropriateness
Drugs/Diseases

Util A	Util B	Util C **(Include)**
EVG/c/FTC/TAF		Cirrhosis

References:
Genvoya Prescribing Information, November 2015, Gilead Sciences, Inc.
Clinical Pharmacology, 2015 Elsevier/Gold Standard.

24. Genvoya / All Other Antiretrovirals ____√____ _____ _____

Alert Message: Genvoya (EVG/c/FTC/TAF) is a combination product that is a complete HIV treatment regimen. The use of this other antiretroviral agents with EVG/c/FTC/TAF should be avoided.

Conflict Code: TA – Therapeutic Appropriateness
Drugs/Diseases

Util A	Util B	Util C
EVG/c/FTC/TAF	Protease Inhibitors	
	CCR5	
Fusion Inhibitor		
Integrase Inhibitors		
NNRTIs		
NRTIs		
NARTI		
ART Boosting Agent		

References:
Genvoya Prescribing Information, November 2015, Gilead Sciences, Inc.
Clinical Pharmacology, 2015 Elsevier/Gold Standard.

Criteria Recommendations	*Accepted*	*Approved As Amended*	*Rejected*

25. Genvoya / Drugs Contraindicated with Genvoya ____√____ _____ _____

Alert Message: A review of recent pharmacy claims shows that the patient is receiving concurrent therapy with Genvoya (EVG/c/FTC/TAF) and a drug that is contraindicated with the combination antiretroviral agent. Co-administration of EVG/c/FTC/TAF and the identified agent may result in serious and/or life-threatening events.

Conflict Code: DD – Drug/Drug Interaction
Drugs/Diseases

Util A	Util B		Util C
EVG/c/FTC/TAF	Alfuzosin	Pimozide	
Carbamazepine	Revatio		
Phenobarbital	Triazolam		
Phenytoin	Midazolam Oral		
Rifampin	Ergotamine		
Lovastatin	Dihydroergotamine		
Simvastatin	Methylergonovine		

References:
Genvoya Prescribing Information, November 2015, Gilead Sciences, Inc.

26. Genvoya / Drugs Affecting Renal Function ____√____ _____ _____

Alert Message: A review of recent pharmacy claims shows that the patient is receiving concurrent therapy with Genvoya (EVG/c/FTC/TAF) and a drug that affects renal function. The emtricitabine (FTC) and tenofovir (TAF) components of the fixed combination product EVG/c/FTC/TAF are primarily excreted by the kidneys and co-administration with drugs that reduce renal function or compete for active tubular secretion may increase concentrations of FTC and TAF increasing the risk of adverse reactions.

Conflict Code: DD – Drug/Drug Interaction
Drugs/Diseases

Util A	Util B			Util C
EVG/c/FTC/TAF	Acyclovir	Everolimus	Methotrexate	
	Valacyclovir	Aspirin	Allopurinol	
	Valganciclovir	Acetaminophen		
	Lithium	ACEIs		
	Cyclosporine	ARBs		
	Tacrolimus	NSAIDS		

References:
Genvoya Prescribing Information, November 2015, Gilead Sciences, Inc.

Criteria Recommendations	*Accepted*	*Approved As Amended*	*Rejected*

27. Genvoya / 3A4, 2D6, P-gp, BCRP OATP1B1 & OATP1B3 Substrates ____√____ _____ _____

Alert Message: The cobicistat component of Genvoya (EVG/c/FTC/TAF) is a potent inhibitor of the isoenzymes CYP3A4 and CYP2D6 and the transporters P-gp, BCRP, OATP1B1, and OATP1B3. Concomitant use of EVG/c/FTC/TAF with drugs that are primarily substrates for these isoenzymes and/or transporters may result in elevated substrate plasma concentrations and increased risk of substrate-related adverse effects.

Conflict Code: DD – Drug/Drug Interaction
Drugs/Diseases

Util A	Util B		Util C
EVG/c/FTC/TAF	Amiodarone	Zolpidem	
	Bupropion	Lapatinib	
	Canagliflozin	Pazopanib	
	Digoxin	Imatinib	
Boceprevir	Topotecan		
	Chlorpromazine	Methotrexate	
	Disopyramide	SSRIs	
	Flecainide	TCAs	
	Propafenone	Methadone	
	Quinidine	Oxycodone	
	Tamoxifen	Hydrocodone	
	Trazodone	Codeine	

References:
Genvoya Prescribing Information, November 2015, Gilead Sciences, Inc.
Clinical Pharmacology, 2016 Elsevier/Gold Standard.

Criteria Recommendations	*Accepted*	*Approved As Amended*	*Rejected*

28. Genvoya / CYP2C9 Substrates ____√____ _____ _____

Alert Message: The elvitegravir component of Genvoya (EVG/c/FTC/TAF) is a modest inducer of CYP2C9 and concurrent use of EVG/c/FTC/TAF with drugs that are primarily substrates for CYP2C9 may result in elevated substrate plasma concentrations and increased risk of substrate-related adverse effects.

Conflict Code: DD – Drug/Drug Interaction
Drugs/Diseases

Util A	Util B		Util C
EVG/c/FTC/TAF	Amitriptyline	Mefenamic Acid	
	Carvedilol	Meloxicam	
	Celecoxib	Montelukast	
	Chlorpheniramine	Nateglinide	
	Diclofenac	Piroxicam	
	Dronabinol	Quetiapine	
	Fluoxetine	Rosiglitazone	
	Fluvastatin	Tamoxifen	
	Glipizide	Tolbutamide	
	Ibuprofen	Torsemide	
	Imipramine	Valsartan	
	Indomethacin	Warfarin	
	Irbesartan	Zafirlukast	
	Losartan	Zileuton	

References:
Genvoya Prescribing Information, November 2015, Gilead Sciences, Inc.
Clinical Pharmacology, 2016 Elsevier/Gold Standard.
Evidence-Based Medicine (EBM) CONSULT Cytochrome P450 (CP450) Drug Reference Table – Medication Substrates
Available at: http://www.ebmconsult.com/content/pages/cytochrome-cyp-p450-enzyme-medication-herbs-substrates

29. Genvoya / Clarithromycin / CKD Stage 2 & 3 ____√____ _____ _____

Alert Message: The concurrent use of Genvoya (EVG/c/FTC/TAF) with clarithromycin may result in increased plasma concentrations of both clarithromycin and the cobicistat component of the combo antiretroviral. While no clarithromycin dosage adjustment is required for patients with CLcr 60 ml/min or greater, patients with CLcr 50 to 60 ml/min should have the clarithromycin dose reduced by 50%. Clarithromycin and cobicistat are CYP3A4 substrates as well as inhibitors and clarithromycin is renally eliminated.

Conflict Code: DD – Drug/Drug Interaction
Drugs/Diseases

Util A	Util B	Util C **(Include)**
EVG/c/FTC/TAF	Clarithromycin	CKD Stage 2 & 3

References:
Genvoya Prescribing Information, November 2015, Gilead Sciences, Inc.

Criteria Recommendations	*Accepted*	*Approved As Amended*	*Rejected*

30. Genvoya / Telithromycin ____√____ _____ _____

Alert Message: The concurrent use of Genvoya (EVG/c/FTC/TAF) with telithromycin may result in elevated plasma concentrations of telithromycin and/or the cobicistat component of the combo antiretroviral increasing the risk of adverse effects. Telithromycin and cobicistat are CYP3A4 substrates as well as inhibitors. Consider monitoring the patient for adverse effects of both medications.

Conflict Code: DD – Drug/Drug Interaction
Drugs/Diseases

Util A	Util B	Util C
EVG/c/FTC/TAF	Telithromycin	

References:
Genvoya Prescribing Information, November 2015, Gilead Sciences, Inc.

31. Genvoya / Oxcarbazepine ____√____ _____ _____

Alert Message: The concurrent use of Genvoya (EVG/c/FTC/TAF) with oxcarbazepine may result in decreased plasma concentrations of the elvitegravir (EVG) and cobicistat (c) components of the combo antiretroviral which may result in loss of antiretroviral efficacy and potential development of viral resistance. Elvitegravir and cobicistat are CYP3A4 substrates and oxcarbazepine is a CYP3A4 inducer. Alternative anticonvulsants should be considered for patients prescribed EVG/c/FTC/TAF.

Conflict Code: DD – Drug/Drug Interaction
Drugs/Diseases

Util A	Util B	Util C
EVG/c/FTC/TAF	Oxcarbazepine	

References:
Genvoya Prescribing Information, November 2015, Gilead Sciences, Inc.

32. Genvoya / Ethosuximide ____√____ _____ _____

Alert Message: The concurrent use of Genvoya (EVG/c/FTC/TAF) with ethosuximide may result in elevated plasma concentrations of ethosuximide due to inhibition, by the cobicistat component, of ethosuximide CYP3A4-mediated metabolism. Clinical monitoring is recommended with concomitant use.

Conflict Code: DD – Drug/Drug Interaction
Drugs/Diseases

Util A	Util B	Util C
EVG/c/FTC/TAF	Ethosuximide	

References:
Genvoya Prescribing Information, November 2015, Gilead Sciences, Inc.

Criteria Recommendations	*Accepted*	*Approved As Amended*	*Rejected*

33. Genvoya / Rifabutin & Rifapentine ___√_____ _____ _____

Alert Message: The concurrent use of Genvoya (EVG/c/FTC/TAF) with rifabutin or rifapentine is not recommended due to potential for loss of virologic response. Both rifabutin and rifapentine are inducers of CYP3A4-mediated metabolism and co-administration may result in the decreased plasma concentrations of the components which are CYP3A4 substrates (cobicistat, elvitegravir, and tenofovir) in the fixed dosed combination product EVG/c/FTC/TAF.

Conflict Code: DD – Drug/Drug Interaction
Drugs/Diseases

Util A	Util B	Util C
EVG/c/FTC/TAF	Rifabutin	
	Rifapentine	

References:
Genvoya Prescribing Information, November 2015, Gilead Sciences, Inc.

34. Genvoya / Certain Benzodiazepines ____√_____ _____ _____

Alert Message: Concurrent use of Genvoya (EVG/c/FTC/TAF) with benzodiazepines that are metabolized via CYP3A4 may result in elevated benzodiazepine levels increasing the risk of benzodiazepine-related adverse effects. The cobicistat component of EVG/c/FTC/TAF is a potent inhibitor of the CYP3A4 isoenzyme. Clinical monitoring for benzodiazepine-related adverse effects is recommended and a dosage reduction may be necessary.

Conflict Code: DD – Drug/Drug Interaction
Drugs/Diseases

Util A	Util B	Util C
EVG/c/FTC/TAF	Alprazolam	
	Chlordiazepoxide	
	Clonazepam	
	Clorazepate	
	Diazepam	
	Estazolam	
	Flurazepam	
	Quazepam	

References:
Genvoya Prescribing Information, November 2015, Gilead Sciences, Inc.

Criteria Recommendations	*Accepted*	*Approved As Amended*	*Rejected*

35. Genvoya / Beta-Blockers - CYP3A4, CYP2D6 & P-gp Substrates ____√____ _____ _____

Alert Message: The cobicistat component of Genvoya (EVG/c/FTC/TAF) is a potent inhibitor of the isoenzymes CYP3A4 and CYP2D6 and the transporters P-gp, BCRP, OATP1B1, and OATP1B3. Concomitant use of EVG/c/FTC/TAF with beta-blockers that are primarily substrates for these isoenzymes and/or transporters may result in elevated beta-blocker plasma concentrations. Clinical monitoring is recommended and a dosage decrease of the beta-blocker may be necessary.

Conflict Code: DD – Drug/Drug Interaction
Drugs/Diseases

Util A	Util B	Util C
EVG/c/FTC/TAF	Metoprolol - 2D6	
	Timolol - 2D6	
	Bisoprolol - 2D6 & 3A4	
	Nadolol - P-glycoprotein	
	Nebivolol - 2D6	
	Pindolol - 2D6	
	Propranolol - 2D6	

References:
Genvoya Prescribing Information, November 2015, Gilead Sciences, Inc.

36. Genvoya / CCBs - CYP3A4, CYP2D6 & P-gp Substrates ____√____ _____ _____

Alert Message: The cobicistat component of Genvoya (EVG/c/FTC/TAF) is a potent inhibitor of the isoenzymes CYP3A4 and CYP2D6 and the transporters P-gp, BCRP, OATP1B1, and OATP1B3. Concomitant use of EVG/c/FTC/TAF with calcium channel blockers (CCBs) that are primarily substrates for these isoenzymes and/or transporters may result in elevated CCB plasma concentrations. Clinical monitoring is recommended upon co-administration of these agents.

Conflict Code: DD – Drug/Drug Interaction
Drugs/Diseases

Util A	Util B	Util C
EVG/c/FTC/TAF	Amlodipine - 3A4	
	Diltiazem - 2D6 & 3A4	
	Felodipine - 3A4	
	Isradipine -3A4	
	Nicardipine - 2D6 & 3A4	
	Nifedipine - 2D6 & 3A4	
	Nimodipine - 3A4	
	Nisoldipine - 3A4	
	Verapamil - 2D6 & 3A4 & P-gp	

References:
Genvoya Prescribing Information, November 2015, Gilead Sciences, Inc.

Criteria Recommendations	*Accepted*	*Approved As Amended*	*Rejected*

37. Genvoya / Dexamethasone ____√____ _____ _____

Alert Message: The concurrent use of Genvoya (EVG/c/FTC/TAF) with dexamethasone may result in decreased plasma concentrations of the elvitegravir and cobicistat components of the combo antiretroviral which may result in loss of antiretroviral efficacy and potential development of viral resistance. Elvitegravir and cobicistat are CYP3A4 substrates and dexamethasone is a CYP3A4 inducer. Alternative corticosteroid therapy should be considered for patients prescribed EVG/c/FTC/TAF.

Conflict Code: DD – Drug/Drug Interaction
Drugs/Diseases

Util A	Util B	Util C
EVG/c/FTC/TAF	Dexamethasone	

References:
Genvoya Prescribing Information, November 2015, Gilead Sciences, Inc.

38. Genvoya / Fluticasone ____√____ _____ _____

Alert Message: The concurrent use of Genvoya (EVG/c/FTC/TAF) with a fluticasone-containing product may cause increased fluticasone plasma concentrations due to inhibition of fluticasone CYP3A4-mediated metabolism by the cobicistat component of the antiretroviral product. Concomitant therapy may result in adverse systemic corticosteroid effects. Alternative corticosteroids should be considered, particularly for long-term use.

Conflict Code: DD – Drug/Drug Interaction
Drugs/Diseases

Util A	Util B	Util C
EVG/c/FTC/TAF	Fluticasone	

References:
Genvoya Prescribing Information, November 2015, Gilead Sciences, Inc.

39. Genvoya / Atorvastatin ____√____ _____ _____

Alert Message: The concurrent use of Genvoya (EVG/c/FTC/TAF) with atorvastatin may result in increased plasma concentrations of atorvastatin due to inhibition, by cobicistat component of the antiretroviral, of atorvastatin CYP3A4-mediated metabolism. When prescribing atorvastatin with EVG/c/FTC/TAF initiate atorvastatin at the lowest starting dose and titrate carefully while monitoring for safety.

Conflict Code: DD – Drug/Drug Interaction
Drugs/Diseases

Util A	Util B	Util C
EVG/c/FTC/TAF	Atorvastatin	

References:
Genvoya Prescribing Information, November 2015, Gilead Sciences, Inc.

Criteria Recommendations	*Accepted*	*Approved As Amended*	*Rejected*

40. Genvoya / Norgestimate/Ethinyl Estradiol OCs ____√____ _____ _____

Alert Message: The concurrent use of Genvoya (EVG/c/FTC/TAF) with a norgestimate/estradiol oral contraceptive may result in increased plasma concentrations of norgestimate and decreased concentrations of ethinyl estradiol. The effects of elevated norgestimate concentrations are not fully known and can include increased risk of insulin resistance, dyslipidemia, and venous thrombosis. The potential risks and benefits associated with co-administration of these agents should be considered, particularly in women who have risk factors for these events.

Conflict Code: DD – Drug/Drug Interaction
Drugs/Diseases

Util A	Util B	Util C
EVG/c/FTC/TAF	Norgestimate/Ethinyl Estradiol OCs	

References:
Genvoya Prescribing Information, November 2015, Gilead Sciences, Inc.

41. Genvoya / Immunosuppressants ____√____ _____ _____

Alert Message: The cobicistat component of Genvoya (EVG/c/FTC/TAF) is a potent inhibitor of the isoenzyme CYP3A4 and a p-glycoprotein (P-gp) inhibitor. Concomitant use of EVG/c/FTC/TAF with an immunosuppressant that is a substrate of CYP3A4 or P-gp may result in elevated immunosuppressant plasma concentrations. Therapeutic monitoring is recommended if these agents are co-administered.

Conflict Code: DD – Drug/Drug Interaction
Drugs/Diseases

Util A	Util B	Util C
EVG/c/FTC/TAF	Cyclosporine	
	Tacrolimus	
	Sirolimus	
	Everolimus	

References:
Genvoya Prescribing Information, November 2015, Gilead Sciences, Inc.

42. Genvoya / Colchicine / Renal & Hepatic Impairment ____√____ _____ _____

Alert Message: Concurrent use of Genvoya (EVG/c/FTC/TAF) with colchicine may result in elevated colchicine plasma concentrations. If co-administration is necessary use the following dosage adjustment for gout flares: administer a single 0.6 mg dose of colchicine, followed by 0.3 mg 1 hour later, and repeat this treatment course no sooner than 3 days. If used for gout prophylaxis and the original regimen was 0.6 mg BID, reduce dose to 0.3 mg QD. If regimen was 0.6 mg QD, reduce to 0.3 mg QOD. If used for familial Mediterranean fever the maximum daily dose is 0.6 mg.

Conflict Code: DD – Drug/Drug Interaction
Drugs/Diseases

Util A	Util B	Util C **(Negate)**
EVG/c/FTC/TAF	Colchicine	Renal Impairment
		Hepatic Impairment

References:
Genvoya Prescribing Information, November 2015, Gilead Sciences, Inc.

Criteria Recommendations	*Accepted*	*Approved As Amended*	*Rejected*

43. Genvoya / Antipsychotic ____√____ _____ _____

Alert Message: The cobicistat component of Genvoya (EVG/c/FTC/TAF) is a potent inhibitor of the isoenzymes CYP3A4 and CYP2D6. Concomitant use of EVG/c/FTC/TAF with antipsychotics that are primarily substrates for these isoenzymes may result in elevated antipsychotic plasma concentrations. A decrease in the dosage of the antipsychotic may be needed when co-administered with EVG/c/FTC/TAF.

Conflict Code: DD – Drug/Drug Interaction
Drugs/Diseases

Util A	Util B	Util C
EVG/c/FTC/TAF	Aripiprazole	Chlorpromazine
Asenapine	Fluphenazine	
Brexpiprazole	Haloperidol	
Cariprazine	Perphenazine	
Clozapine	Thioridazine	
Iloperidone		
Lurasidone		
Olanzapine		
Paliperidone		
Quetiapine		
Risperidone		
Ziprasidone		

References:
Genvoya Prescribing Information, November 2015, Gilead Sciences, Inc.

44. Genvoya / Itraconazole & Ketoconazole ____√____ _____ _____

Alert Message: The concurrent use of Genvoya (EVG/c/FTC/TAF) with ketoconazole or itraconazole may result in elevated plasma levels of the antifungal and the cobicistat component of the combination product. The maximum daily dose of ketoconazole or itraconazole should not exceed 200 mg per day when administered with (EVG/c/FTC/TAF). Both antifungals and the cobicistat component of EVG/c/FTC/TAF are CYP3A4 substrates as well as strong CYP3A4 inhibitors.

Conflict Code: DD – Drug/Drug Interaction
Drugs/Diseases

Util A	Util B	Util C **(Include)**
Itraconazole		EVG/c/FTC/TAF
Ketoconazole		

Max Dose: 200 mg/day

References:
Genvoya Prescribing Information, November 2015, Gilead Sciences, Inc.

Criteria Recommendations	*Accepted*	*Approved As Amended*	*Rejected*
45. Genvoya / Voriconazole	___√___	_____	_____

Alert Message: The concurrent use of Genvoya (EVG/c/FTC/TAF) with voriconazole may result in elevated plasma levels of voriconazole and the cobicistat component of the combination product. Both voriconazole and the cobicistat component of EVG/c/FTC/TAF are CYP3A4 substrates as well as strong CYP3A4 inhibitors. Co-administration is not recommended unless benefit/risk assessment justifies the use.

Conflict Code: DD – Drug/Drug Interaction
Drugs/Diseases

Util A	Util B	Util C
EVG/c/FTC/TAF	Voriconazole	

References:
Genvoya Prescribing Information, November 2015, Gilead Sciences, Inc.

Stephanie McGee Azar, Commissioner — (X) Approve ( ) Deny — 3/9/17 Date

Robert Moon, M.D., Deputy Commissioner and Medical Director — (X) Approve ( ) Deny — 3-8-17 Date

Kathy Hall, Deputy Commissioner — (X) Approve ( ) Deny — March 6, 2017 Date