Kentucky Pharmacy and Therapeutics Committee Meeting Minutes

December 7, 2016
1:00 p.m. EST

Attendees:

Peter Thurman
Robert Dinwiddie
Andrew Rudd
Nancy Redmon
Joe Yocum
Andrew Odenweld
Amy Cranfill

- **SELF INJECTED EPINEPHRINE**

Review Date	3Q16
Clinical Review:	Self Injected Epinephrine
Reason for Review:	• Category review
PRODUCTS INCLUDED IN THE REVIEW: AUTHORIZED GENERIC EPINEPHRINE, EPINEPHRINE 0.15 MG AUTO-INJCT, EPINEPHRINE 0.3 MG AUTO-INJECT, EPIPEN 2-PAK 0.3 MG AUTO-INJCT, EPIPEN JR 2-PAK 0.15 MG INJCTR, EPINEPHRINE 1 MG/ML AMPUL (Brand), EPINEPHRINE 0.1 MG/ML SYRINGE , EPINEPHRINE 1 MG/ML VIAL, EPINEPHRINE 1 MG/ML AMPUL (Generic)	
CURRENT PREFERRED PRODUCTS: EPIPEN, EPIPEN JR	
RECOMMENDATION: • Epinephrine 0.15 mg auto-inject will move from Non-Preferred to Preferred • Epinephrine 0.3 mg auto-inject will move from Non-Preferred to Preferred • Epinephrine 0.1 mg/ml syringe will move from Non-Preferred to Preferred • Epinephrine 1 mg/ml vial will move from Non-Preferred to Preferred	

- **LONG ACTING INSULIN THERAPY**

Review Date	3Q16
Clinical Review:	Long Acting Insulin's
Reason for Review:	• Category review/New Drug Review
PRODUCTS INCLUDED IN THE REVIEW: BASAGLAR KWIKPEN, LANTUS 100 UNITS/ML VIAL, LANTUS SOLOSTAR 100 UNITS/ML, LEVEMIR 100 UNITS/ML VIAL, LEVEMIR FLEXTOUCH 100 UNITS/ML, TOUJEO SOLOSTAR 300 UNITS/ML	
CURRENT PREFERRED PRODUCTS: LANTUS 100 UNITS/ML VIAL, LANTUS SOLOSTAR 100 UNITS/ML	

RECOMMENDATION:

1. Basaglar Kwikpen will be Preferred
   - Lantus vial will move from Preferred to Non-Preferred
   - Lantus Solostar will move from Preferred to Non-Preferred

• SEROTONIN AND NOREPINEPHRINE REUPTAKE INHIBITORS (SNRIs)/NEUROPATHIC PAIN

Review Date	3Q16
Clinical Review:	Serotonin and Norepinephrine Reuptake Inhibitors (SNRIs)/Neuropathic Pain
Reason for Review:	• Category Review

PRODUCTS INCLUDED IN THE REVIEW: AMITRIPTYLINE HCL 10 MG TAB, AMITRIPTYLINE HCL 100 MG TAB , AMITRIPTYLINE HCL 150 MG TAB, AMITRIPTYLINE HCL 25 MG TAB, AMITRIPTYLINE HCL 50 MG TAB AMITRIPTYLINE HCL 75 MG TAB, DESVENLAFAXINE ER 100 MG TAB, DESVENLAFAXINE ER 100 MG TAB DESVENLAFAXINE ER 50 MG TAB, DESVENLAFAXINE ER 50 MG TABLET, DESVENLAFAXINE FUM ER 100 MG, DESVENLAFAXINE FUM ER 50 MG, DULOXETINE HCL DR 20 MG CAP, DULOXETINE HCL DR 30 MG CAP DULOXETINE HCL DR 40 MG CAP, DULOXETINE HCL DR 60 MG CAP, FETZIMA 20-40 MG TITRATION PAK FETZIMA ER 120 MG CAPSULE, FETZIMA ER 20 MG CAPSULE, FETZIMA ER 40 MG CAPSULE, FETZIMA ER 80 MG CAPSULE,GABAPENTIN 100 MG CAPSULE, GABAPENTIN 250 MG/5 ML SOLN, GABAPENTIN 250 MG/5 ML SOLN, GABAPENTIN 300 MG CAPSULE, GABAPENTIN 300 MG/6 ML SOLN, GABAPENTIN 400 MG CAPSULE, GABAPENTIN 600 MG TABLET,GABAPENTIN 800 MG TABLET, LIDOCAINE 5% PATCH, LYRICA 100 MG CAPSULE, LYRICA 150 MG CAPSULE, LYRICA 20 MG/ML ORAL SOLUTION, LYRICA 200 MG CAPSULE LYRICA 225 MG CAPSULE, LYRICA 25 MG CAPSULE, LYRICA 300 MG CAPSULE, LYRICA 50 MG CAPSULE LYRICA 75 MG CAPSULE, PRISTIQ ER 100 MG TABLET, PRISTIQ ER 25 MG TABLET, PRISTIQ ER 50 MG TABLET, SAVELLA 100 MG TABLET, SAVELLA 12.5 MG TABLET, SAVELLA 25 MG TABLET, SAVELLA 50 MG TABLET, SAVELLA TITRATION PACK, VENLAFAXINE HCL 100 MG TABLET, VENLAFAXINE HCL 25 MG TABLET, VENLAFAXINE HCL 37.5 MG TABLET, VENLAFAXINE HCL 50 MG TABLET, VENLAFAXINE HCL 75 MG TABLET, VENLAFAXINE HCL ER 150 MG CAP, VENLAFAXINE HCL ER 150 MG TAB, VENLAFAXINE HCL ER 150 MG TAB, VENLAFAXINE HCL ER 225 MG TAB, VENLAFAXINE HCL ER 225 MG TAB, VENLAFAXINE HCL ER 37.5 MG CAP, VENLAFAXINE HCL ER 37.5 MG TAB, VENLAFAXINE HCL ER 37.5 MG TAB, VENLAFAXINE HCL ER 75 MG CAP, VENLAFAXINE HCL ER 75 MG TAB, VENLAFAXINE HCL ER 75 MG TAB

CURRENT PREFERRED PRODUCTS: AMITRIPTYLINE HCL 10 MG TAB , AMITRIPTYLINE HCL 100 MG TAB, AMITRIPTYLINE HCL 150 MG TAB, AMITRIPTYLINE HCL 25 MG TAB, AMITRIPTYLINE HCL 50 MG TAB AMITRIPTYLINE HCL 75 MG TAB, GABAPENTIN 100 MG CAPSULE, GABAPENTIN 250 MG/5 ML SOLN GABAPENTIN 250 MG/5 ML SOLN, GABAPENTIN 300 MG CAPSULE, GABAPENTIN 300 MG/6 ML SOLN GABAPENTIN 400 MG CAPSULE, GABAPENTIN 600 MG TABLET, GABAPENTIN 800 MG TABLET LIDOCAINE 5% PATCH, VENLAFAXINE HCL 100 MG TABLET, VENLAFAXINE HCL 25 MG TABLET VENLAFAXINE HCL 37.5 MG TABLET, VENLAFAXINE HCL 50 MG TABLET, VENLAFAXINE HCL 75 MG TABLET VENLAFAXINE HCL ER 150 MG CAP, VENLAFAXINE HCL ER 150 MG TAB , VENLAFAXINE HCL ER 225 MG TAB, VENLAFAXINE HCL ER 37.5 MG CAP, VENLAFAXINE HCL ER 37.5 MG TAB, VENLAFAXINE HCL ER 75 MG CAP, VENLAFAXINE HCL ER 75 MG TAB

RECOMMENDATION:

- No Changes

• ORAL SKELETAL MUSCLE RELAXANTS

Review Date	3Q16

Clinical Review:	• Oral Skeletal Muscle Relaxants
Reason for Review:	• Category review
PRODUCTS INCLUDED IN THE REVIEW: BACLOFEN 10 MG TABLET, BACLOFEN 20 MG TABLET CARISOPRODOL 250 MG TABLET, CARISOPRODOL 350 MG TABLET, CHLORZOXAZONE 500 MG TABLET CYCLOBENZAPRINE 10 MG TABLET, CYCLOBENZAPRINE 5 MG TABLET, CYCLOBENZAPRINE 7.5 MG TABLET, DANTROLENE SODIUM 100 MG CAP, DANTROLENE SODIUM 25 MG CAP, DANTROLENE SODIUM 50 MG CAP, METAXALONE 400 MG TABLET, METAXALONE 800 MG TABLET, METHOCARBAMOL 500 MG TABLET, METHOCARBAMOL 750 MG TABLET, ORPHENADRINE ER 100 MG TABLE, TIZANIDINE HCL 2 MG CAPSULE, TIZANIDINE HCL 2 MG TABLET, TIZANIDINE HCL 4 MG CAPSULE, TIZANIDINE HCL 4 MG TABLET TIZANIDINE HCL 6 MG CAPSULE	
CURRENT PREFERRED PRODUCTS: BACLOFEN 10 MG TABLET, BACLOFEN 20 MG TABLET CARISOPRODOL 250 MG TABLET, CARISOPRODOL 350 MG TABLET, CHLORZOXAZONE 500 MG TABLET CYCLOBENZAPRINE 10 MG TABLET, CYCLOBENZAPRINE 5 MG TABLET, DANTROLENE SODIUM 100 MG CAP, DANTROLENE SODIUM 25 MG CAP, DANTROLENE SODIUM 50 MG CAP, METHOCARBAMOL 500 MG TABLET, METHOCARBAMOL 750 MG TABLET, ORPHENADRINE ER 100 MG TABLET, TIZANIDINE HCL 2 MG CAPSULE, TIZANIDINE HCL 2 MG TABLET, TIZANIDINE HCL 4 MG CAPSULE, TIZANIDINE HCL 4 MG TABLET TIZANIDINE HCL 6 MG CAPSULE	
RECOMMENDATION: • Tizanidine 2 mg capsule will move from Preferred to Non-Preferred • Tizanidine 4 mg capsule will move from Preferred to Non-Preferred • Tizanidine 6 mg capsule will move from Preferred to Non-Preferred	

- **OTIC ANTIBIOTICS**

Review Date	3Q16
Clinical Review:	Otic Antibiotics
Reason for Review:	• Category review
PRODUCTS INCLUDED IN THE REVIEW: CETRAXAL 0.2% EAR SOLUTION, CIPRO HC OTIC SUSPENSION CIPRODEX OTIC SUSPENSION, CIPROFLOXACIN 0.2% OTIC SOLN, COLY-MYCIN S OTIC SUSP DROP CORTISPORIN-TC OTIC, FLOXIN 0.3% EAR DROPS, NEOMYCIN-POLYMYXIN-HC EAR SOLN, NEOMYCIN-POLYMYXIN-HC EAR SOLN, NEOMYCIN-POLYMYXIN-HC EAR SUSP, OFLOXACIN 0.3% EAR DROPS	
CURRENT PREFERRED PRODUCTS: CIPRODEX OTIC SUSPENSION**,** CIPROFLOXACIN 0.2% OTIC SOLN NEOMYCIN-POLYMYXIN-HC EAR SOLN, NEOMYCIN-POLYMYXIN-HC EAR SOLN, NEOMYCIN-POLYMYXIN-HC EAR SUSP, OFLOXACIN 0.3% EAR DROPS	
RECOMMENDATION: • Ciprodex Otic Suspension will move from Preferred to Non-Preferred • Floxin 0.3% Ear Drops to be aligned as Preferred	

- **ACNE – BENZOYL PEROXIDE COMBOS**

Review Date	3Q16
Clinical Review:	Acne – Benzoyl Peroxide Combos

Reason for Review:	• Category review
PRODUCTS INCLUDED IN THE REVIEW: ACANYA GEL PUMP, BENZACLIN GEL, BENZACLIN GEL 35G PUMP BENZACLIN GEL 50G PUMP, BENZAMYCIN GEL, BENZAMYCINPAK GEL, BENZAMYCINPAK GEL CLIND PH-BENZOYL PEROX 1.2-5% , CLINDA-BENZOYL PEROX 1-5% PUMP, CLINDACIN ETZ KIT CLINDACIN PAC KIT, CLINDAMYCIN-BENZOYL PEROX 1-5%, DUAC 1.2-5% GEL, DUAC GEL EPIDUO 0.1-2.5% GEL, EPIDUO 0.1-2.5% GEL PUMP, EPIDUO FORTE 0.3-2.5% GEL PUMP ERYTHROMYCIN-BENZOYL GEL, INOVA 4% EASY PAD, INOVA 4-1 EASY PAD, INOVA 8% EASY PAD INOVA 8-2 EASY PAD, NEUAC 1.2-5% KIT, NEUAC GEL, ONEXTON GEL PUMP, VANOXIDE-HC LOTION VELTIN 1.2%-0.025% GEL, ZIANA GEL	
CURRENT PREFERRED PRODUCTS: ERYTHROMYCIN-BENZOYL GEL	
RECOMMENDATION: • Clindamycin Ph-Benzoyl Peroxide 1.2-5% gel will move from Non-Preferred To Preferred • Clindamycin-Benzoyl Peroxide 1-5% Pump will move from Non-Preferred To Preferred • Clindamycin-Benzoyl Peroxide 1-5% gel will move from Non-Preferred To Preferred • Erythromycin-Benzoyl Gel will move from Preferred to Non-Preferred	

- **EMERGENCY CONTRACEPTIVES**

Review Date	3Q16
Clinical Review:	Emergency Contraceptives
Reason for Review:	• Category review
PRODUCTS INCLUDED IN THE REVIEW: ECONTRA EZ 1.5 MG TABLET**,** ELLA 30 MG TABLET FALLBACK SOLO 1.5 MG TABLET, LEVONORGESTREL 1.5 MG TABLET, MY WAY 1.5 MG TABLET, NEXT CHOICE ONE DOSE 1.5 MG TB**,** OPCICON ONE-STEP 1.5 MG TABLET**,** PLAN B ONE-STEP 1.5 MG TABLET PLAN B ONE-STEP 1.5 MG TABLET, REACT 1.5 MG TABLET, TAKE ACTION 1.5 MG TABLET	
CURRENT PREFERRED PRODUCTS: ECONTRA EZ 1.5 MG TABLET, FALLBACK SOLO 1.5 MG TABLET LEVONORGESTREL 1.5 MG TABLET, MY WAY 1.5 MG TABLET, NEXT CHOICE ONE DOSE 1.5 MG TB, OPCICON ONE-STEP 1.5 MG TABLET	
RECOMMENDATION: • Ella 30 mg tablet will move from Non-Preferred to Preferred • React 1.5 mg will move from Non-Preferred to Preferred	

- **ANTI-EMETICS**

Review Date	3Q16
Clinical Review:	Anti-Emetics
Reason for Review:	• Alignment
PRODUCTS INCLUDED IN THE REVIEW: EMEND TRIPACK, EMEND 40 MG CAPSULE, EMEND 80 MG CAPSULE, EMEND 125 MG CAPSULE	
CURRENT PREFERRED PRODUCTS: Ondasetron ODT**,** EMEND TRIPACK, EMEND 40 MG CAPSULE EMEND 80 MG CAPSULE, EMEND 125 MG CAPSULE	
RECOMMENDATION:	

- Emend Tripack to be aligned as Non-Preferred
- Emend 40 mg capsule to be aligned as Non-Preferred
- Emend 80 mg capsule to be aligned as Non-Preferred
- Emend 125 mg capsule to be aligned as Non-Preferred

- **LANCETS**

Review Date	3Q16
Clinical Review:	Lancets
Reason for Review:	• Category Review
PRODUCTS INCLUDED IN THE REVIEW: MANUFACTURER US DIAGNOSTICS	
CURRENT PREFERRED PRODUCTS: MANUFACTURER: ACCESS LLC, AGAMATRIX; INC., ARKRAY USA BIONIME USA COR, CAN-AM/ACCESS C, CARDIOCOM MULTI, CHAIN DRUG, CVS, ENTRA HEALTH SY FORA CARE INC., GOOD NEIGHBOR, INVACARE SUPPLY, KROGER/PERRIGO, MCKESSON DRUG MED PLASTIC DEV, MEIJER INC., MHC MEDICAL PRO, NIPRO DIAG/TRIV, OWEN MUMFORD US PERRIGO DIABETE, RITE AID CORP., STERILANCE MEDI, TARGET, US DIAGNOSTICS, VIP INTERNATION WALGREEN CO.	
RECOMMENDATION: • US Diagnostics Lancets will move from Preferred to Non-Preferred	

- **NON-PDL**

HIV Therapy

Review Date	3Q16
Clinical Review:	HIV Therapy
Reason for Review:	• Category Review
PRODUCTS INCLUDED IN THE REVIEW: ATRIPLA TABLET, COMPLERA TABLET, INVIRASE 200 MG CAPSULE INVIRASE 500 MG TABLET, LEXIVA 50 MG/ML SUSPENSION, LEXIVA 700 MG TABLET, SUSTIVA 50 MG CAPSULE, SUSTIVA 200 MG CAPSULE, SUSTIVA 600 MG TABLET	
CURRENT PREFERRED PRODUCTS: ATRIPLA TABLET, COMPLERA TABLET, INVIRASE 200 MG CAPSULE INVIRASE 500 MG TABLET, LEXIVA 50 MG/ML SUSPENSION, LEXIVA 700 MG TABLET, SUSTIVA 50 MG CAPSULE, SUSTIVA 200 MG CAPSULE, SUSTIVA 600 MG TABLET	
RECOMMENDATION: • Make all products included in the review Non-PDL	

- **ALIGNMENT**

Ophthalmic Anti-inflammatory Agents

Review Date	3Q16

Clinical Review:	Ophthalmic Anti-inflammatory Agents
Reason for Review:	• Alignment
PRODUCTS INCLUDED IN THE REVIEW: ACUVAIL 0.45% OPHTH SOLUTION, DICLOFENAC 0.1% EYE DROPS, KETOROLAC 0.4% OPHTH SOLUTION, KETOROLAC 0.5% OPHTH SOLUTION	
CURRENT PREFERRED PRODUCTS: FLURBIPROFEN 0.03% EYE DROP**,** PREDNISOLONE AC 1% EYE DROP, PREDNISOLONE SOD 1% EYE DROP, DEXAMETHASONE 0.1% EYE DROP, FLUOROMETHOLONE 0.1% DROPS	
RECOMMENDATION: • Acuvail 0.45% ophth solution to be aligned as Non-Preferred • Diclofenac 0.1% eye drops to be aligned as Preferred • Ketorolac 0.4% ophth solution to be aligned as Non-Preferred • Ketorolac 0.5% ophth solution to be aligned as Non-Preferred	

- **MISCELLANEOUS UTILIZATION MANAGEMENT EDITS**

I. New Opportunities

Mental Healthy Quality Program Duplicate Therapy	
Reason for Review	• Quality program to reduce the risk of overuse and adverse drug events related behavioral health medications. •
Current status	• Not active.
Edit Details	Duplicate Therapy is defined as an individual receiving: • 2 or more tricyclic antidepressant medications; OR • 2 or more typical antipsychotic medications; OR • 2 or more atypical antipsychotic medications; OR • 3 or more antipsychotic medications (total typical plus atypical); OR • 3 or more benzodiazepine medications; OR • 3 or more antidepressant medications, excluding trazodone; OR • 2 or more sedatives/hypnotics, including trazodone; OR • 2 or more SSRI/SNRI antidepressants, excluding bupropion and mirtazapine; OR • 2 or more stimulants having different core ingredients, excluding atomoxetine; OR • 3 or more anticonvulsants or mood stabilizers.
Authorization Criteria	I. Retail pharmacists may obtain approval over the phone where the patient has discontinued one of the medications triggering the prior authorization of benefits request* II. Requests may be approved if the following criteria is met**: I. Prescriptions are for the use of treating epilepsy or a seizure disorder; OR II. Prescriptions are written by, or in consultation with, a psychiatrist; AND III. Prescriptions are for DSM IV diagnosis; AND IV. Prescriptions are for the purpose of tapering or cross tapering III. Any request that do not meet the criteria in Approval Criteria sections I or II will be reviewed for medical necessity. Approval Duration: *One time only – Retail Pharmacy Calls ** One Year approval for all other

Recommendation	**Add duplicate therapy.**

Injectable Anticoagulant Quantity Limit			
Reason for Review	IV. Ensure clinically appropriate use. V. Consistency for the class. QL is active for Arixtra.		
Drug	**Quantity Limit**	**Drug**	**Quantity Limit**
Fragmin 10,000 u/ mL, 12,500 u/ 0.5 ml, 15,000 u/0.6 mL, 18,000 u/0.72 mL Syringe	20 mL per 30 days	Lovenox 60 mg.0.6 mL Syringe	16.8 mL per 28 days
Fragmin 2,500 u/0.2 ml; 5,000 u/0.2 mL Syringe	4 mL per 30 days	Lovenox 80 mg/0.8 mL Syringe	22.4 mL per 28 days
Fragmin 25,000 units/ mL Vial	76 mL per 30 days	Lovenox 100 mg/1 mL	28 mL per 28 days
Fragmin 7,500 units/0.3 mL Syringe	6 mL per 30 days	Lovenox 120 mg/0.8 mL Syringe	22.4 mL per 28 days
Lovenox 30 mg/0.3 mL Syringe	8.4 mL per 28 days	Lovenox 150 mg/mL Syringe	28 mL per 28 days
Lovenox 40 mg/0.4 mL Syringe	11.2 mL per 28 days	Lovenox 300 mg/3 mL Vial, Syringe	84 mL per 28 days
Recommendation	Add QL to brands and generics.		

Niacor Quantity Limit	
Reason for Review	II. Consistency for the class. Other Niacin products have active QL.
Quantity Limit	III. 12 tablets per day.
Recommendation	Add QL.

Inflammatory Bowel Disease Quantity Limits			
Reason for Review	• Prevent waste • Consistency for the class		
Drug	**Quantity Limit**	**Drug**	**Quantity Limit**
Apriso 0.375 g	4 capsules per day	Giazo 1.1 g	6 tablets per day
Azulfidine 500 mg	8 tablets per day	Lialda 1.2 g	4 tablets per day
Azulfidine EN-tabs 500 mg	8 tablets per day	Pentasa 250 mg	16 capsules per day
Canasa 1000 mg	1 suppository per day	Pentasa 500 mg	8 capsules per day
Delzicol 400 mg	6 capsules per day	Rowasa 4 g/60 mL	1680 mL per 28 days
Dipentum 250 mg	4 capsules per day	Uceris 9 mg	1 tablet per day
Entocort EC 3 mg	3 capsules per day		
Recommendation	Add/ Revise QL on brands and generics.		

Dry Eye Prior Authorization and Step Edit	
Reason for Review	• Appropriate use. • Encourage use of lower cost alternatives.
Drug	**Current Status**
Artificial Tears (OTC)	Preferred
Restasis	NP with PA (verifies age and diagnosis)
Xiidra	NP, default NP criteria
Prior Authorization (Restasis, Xiidra)	I. Individual is appropriate age (Xiidra: 17 years of age or older; Restasis: 16 years of age or older); **AND** II. Using to treat moderate to severe dry eye disease; **AND** III. Documentation is provided indicating an abnormal result or response to one or more dry eye disease diagnostic/assessment methods; **AND** I. Individual has had a trial and inadequate response to one artificial tear agent.
Recommendation	Restasis: Revise PA criteria. Xiidra: Add PA Lacrisert: Add step edit criteria.

Dry Eye Quantity Limit	
Reason for Review	I. Prevent waste. II. Cost of Care savings.
Drug	**Quantity Limit**
Lacrisert	2 inserts per day
Restasis	2 vials per day
Xiidra	2 vials per day
Recommendation	Add QL.

Fulyzaq/Mytesi Prior Authorization and Quantity Limit	
Reason for Review	I. Ensure clinically appropriate use. II. Cost of Care savings.
Prior Authorization Criteria Revision	Update Prior Authorization per label/clinical trial inclusion criteria: I. Require occurrence of diarrhea of greater than or equal to one month in duration. II. Require a prior trial with inadequate response to either loperamide or diphenoxylate-atropine. III. Add exclusion for use with a confirmed diagnosis of infectious diarrhea or if infectious causes have not been ruled out.
Quantity Limit	2 tablets per day.
Recommendation	Revise Prior Authorization criteria. Add QL.

Lenvima Prior Authorization	
Reason for Review	• Update with most recent CRC PA criteria and QL
PA criteria	• Update criteria based on FDA-approved label and relevant compendia for accepted off-label use.
Quantity Limit	Lenvima 4 mg caps: Change QL from 1 per day to 2 per day.
	Lenvima 8 mg daily dose packs (New Strength):

	Add QL of 1 pack per 30 days (60 capsules)
	Lenvima 18 mg daily dose packs (New Strength): Add QL of 1 pack per 30 days (90 capsules)
Recommendation	Revise PA criteria. Add/Revise QL.

IV. New UM Edits on New Drugs

Class	Drug	Recommended Edit
GLP-1 Receptor Agonist/Long-Acting Insulin Combination	Soliqua, Xultophy	Step Edit • Individual has had a trial and inadequate response or intolerance to metformin; **OR** • Individual has a contraindication to metformin therapy; **AND** • Individual has had a trial and inadequate response to one preferred GLP-1 receptor agonist; **AND** • Individual has had a trial and inadequate response to one preferred long-acting insulin agent; **AND** • The trials of the GLP-1 receptor agonist and long-acting insulin agent occurred concomitantly; **AND** • Documentation has been provided for why the combination agent is clinically necessary and not for convenience.
Low Potency Topical Corticosteroids	Anti-Itch, Cortizone, Noble Formula HC, Scalp Relief, Scalpicin	Step Edit a. Individual has had a trial and inadequate response or intolerance to 2 preferred topical corticosteroids in the same potency subclass; OR b. The preferred agents are not FDA-approved for the prescribed indication and the requested non-preferred agent is; OR c. The preferred agents are not acceptable due to concomitant clinical situations, such as but not limited to individual requires an alternate dosage form.
Medium Potency Topical Corticosteroids	flurandrenolide cream	
High Potency Topical Corticosteroid	Sernivo	
Very High Potency Topical Corticosteroid	Ultravate lotion	
Antidotes	Cetylev	Prior Authorization • Individuals with acute ingestion of potentially hepatotoxic quantities of acetaminophen.

DPP-4 Combination	Jentadueto XR	Step Edit • trial and inadequate response or intolerance to metformin; OR • Contraindication to metformin Include Jentadueto XR as a preferred product in the non-preferred DPP-4 Step edit. 2.5 mg/ 1000 mg QL: 2 tablets per day 5 mg/ 1000 mg QL: 1 tablet per day
Targeted Immune Modulators	Orencia ClickJect autoinjector	Prior Authorization: Consistent with original injection Step Edit: Requires trial of 2 preferred products. QL: 4 autoinjectors per 28 days
PCS-K9	Repatha 420 mg/3.5 ml prefilled cartridge	Prior Authorization: Consistent with original strength Step Edit: preferred before use of Praluent QL: 1 prefilled cartridge per month
Cancer	Tecentriq	QL: 1 vial per 21 days
ADHD	Adzenys XR ODT	Prior Authorization • Individual is 18 years of age or older; AND • Individual has a diagnosis of attention deficit hyperactivity disorder (ADHD). Adenzys XR ODT 15.7 mg and 18.8 mg are not indicated for adult use. Step Edit • Trial and inadequate response or intolerance to 1 preferred agent; OR • The preferred agent is not FDA-approved for the prescribed indication; OR • The preferred agent is not acceptable due to concomitant clinical conditions. QL: 1 per day
Dementia	Namzaric 7 mg/10 mg, 21 mg/10 mg	Step Edit Criteria • Trial and inadequate response or intolerance to one preferred agent; OR • The preferred agent is not FDA-approved for the prescribed indication and the non-preferred agent is; OR • The preferred agent is not acceptable due to contraindications or concomitant clinical situations. QL: 1 capsule per day
Recommendation	Add PA and/or QL	

V. Revisions to Existing UM Edits

PA Criteria Revisions

Class	Drug	Recommended Edit
Hypersomnia	Xyrem	• For reauthorization, verify individual has met diagnostic criteria for narcolepsy; • Clarify reauthorization requires attestation of clinical efficacy compared to baseline; • Update initial authorization time period to every 3 months to match recommended re-evaluation per the Xyrem REMS; • Update renewal authorization time period to every 6 months.
Cushing's Syndrome	Korlym	• Add continuation of therapy approval criteria requiring patient stabilization or improvement in glucose control. • Add exclusionary criteria based on contraindicated or not recommended concurrent use.
Parkinson's Psychosis	Nuplazid	• Update Prior Authorization to indicate symptoms must be present at least weekly
Short Bowel Syndrome	Gattex	• Add criteria clarifying definition of short bowel syndrome and causative factors. • Add requirement for minimum age of 18 years. • Include exclusionary criteria for use with co-morbid conditions noted as concurrent therapy not recommended or a recommendation to discontinue Gattex therapy.
Substance Use Disorder	Buprenorphine with naloxone	• Remove references to tapering strategy. • Revise maintenance phase requirement for continued psychosocial services
Irritable Bowel Syndrome	Lotronex	• Add requirement for trial of 2 of the following: • Loperamide; OR • Antispasmodics (hyoscyamine, dicyclomine); OR • Tricyclic antidepressants.
Hyperparathyroidism	Sensipar	1. Add accepted off-label indication to treat hypercalcemia in renal transplant recipients with persistent hyperparathyroidism.
Antiviral	Virazole	1. Clarification per label that the individual be an infant or young child
Hereditary Neuropathies	Orfadin	1. Update criteria based on label to require use in combination with dietary restrictions and maintenance of tyrosine plasma level under 500 micromol/L to reduce risk of hypertyrosinemic adverse effects.
Recommendation	Apply PA Criteria Revisions	

Step Edit Revisions

Class	Drug	Recommended Edit
Hyperlipidemics	Advicor, Altoprev, Crestor, Lescol, Lescol XL, Lipitor, Livalo, Mevacor, Pravachol, Simcor, Zocor	2. Change step requirement from trial of one generic to a trial of two preferred agents.
Omega-3 Fatty Acid Agents	Vascepa, Lovaza, Epanova, Omega 3 acid (Rx)	3. Clarify that high intensity statins include atorvastatin 40mg.
Targeted Immune Modulator	Xeljanx XR	4. Add requirement for XR to step through IR in additional to preferred products.
Dementia	Memantine, Donepezil 23mg	5. Add new generic Namenda (memantine) as preferred , and new generic Aricept (donepezil) 23mg as non-preferred in the step edit.
NSAID combo	Duexis, Vimovo	6. Require documentation of 7. inadequate response to the preferred agents; AND 8. inadequate response to the agents prescribed separately; AND 9. the medical reason the combination NSAID/gastroprotective agent is clinically necessary and the same medical reason and clinical benefits are not expected with the individual agents used separately.
	Duexis	10. Add H2 Blockers as an option to try to meet requirement for preferred products.
Phosphate Binder Agents	Auryxia, Eliphos, PhosLo, Phoslyra, Fosrenol, Velphoro	11. Remove general criteria allowing a non-preferred agent when preferred agents have contraindications to use and not associated with the non-preferred agent.
PCS-K9 Agents	Praluent	
Nasal Allergy Spray	Astepro	12. Require documentation of the inadequate response received with generic azelastine and the medical reason a brand azelastine nasal spray agent is clinically necessary, and the same medical reason and clinical benefit is not expected with a generic azelastine nasal spray agent.
Recommendation	Apply Step Edit Revisions	

PA and Step Edit Revisions		
Antihyperlipidemic	Kynamro	1. Add non-approvable criteria for hepatic impairment based on label. 2. Remove general step criteria for overrides for

	Juxtapid	concomitant clinical conditions as no specific clinical conditions are included.
Topical Testosterone and Androgen Agents	Androgel, Androderm, Axiron, Testim, Natesto, Striant, Vogelxo, Fortesta, Testosterone Gel, Vogelxo	1. Add criteria for continuation of therapy for replacement in treatment of hypogonadism consistent with injectable testosterone clinical guideline. 2. Update use in breast cancer to confirm use in premenopausal women who have benefited from oophorectomy. 3. Add criteria for use in female-to-male transgender individuals consistent with injectable testosterone clinical guideline. 4. When step edit applies, remove general step criteria for overrides for concomitant clinical conditions as no specific clinical conditions are included.
Recommendation	Apply PA and Step Edit Revisions	

Quantity Limit and Quantity Override Criteria Revisions

Class	Drug	Recommended Edit
Influenza	Relenza 5mg Diskhaler	1 package (20 each) per dispensing; 1 fill per 90 days
	Tamiflu capsules 30 mg	20 per fill; 1 fill per 90 days
	Tamiflu capsules 45 mg	10 per fill; 1 fill per 90 days
	Tamiflu capsules 75 mg	10 per fill; 1 fill per 90 days
	Tamiflu suspension 6 mg/mL	180 mL per fill; 1 fill per 90 days
Targeted Immune Modifiers	Humira	1. Add approval criteria for additional quantities for initiation of therapy in uveitis (UV) based on label per recent FDA-approval.
Substance Use Disorder	Subutex	1. Remove references to tapering strategy. 2. Revise maintenance phase requirement for continued psychosocial services
Testosterone Replacement	Testosterone 1% 25 mg/ 2.5 gm packet	1. Add override criteria to allow for additional supply consistent with other strengths and

		dosage forms.
Recommendation	Apply QL and QL criteria Revisions	

VI. Medical Policy and Clinical Guidelines

Policy Number	Policy Name	Key Revisions
DRUG.00087	Asfotase alfa (Strensiq™) Replace Pharmacy PA criteria.	Criteria for infantile form of hypophosphatasia when criteria for severe disease are met.
DRUG.00088	Atezolizumab (Tecentriq™) New Drug	Criteria for locally advantage or metastatic urothelial carcinoma following progression with platinum containing chemotherapy.
DRUG.00089	Daclizumab (Zinbryta™) New Drug	Criteria for adults with relapsing-remitting multiple sclerosis refractory to at least 2 agents.
DRUG.00090	Bezlotoxumab (ZINPLAVA™) New Drug- Preliminary Review	Proposed criteria for prevention of symptomatic, confirmed Clostridium difficile recurrence in individuals receiving antibiotic treatment.
DRUG.00092	Probuphine (buprenorphine implant) No paid claims in most recent 12 months.	Criteria for treatment of opioid use disorder following stable sublingual or transmucosal buprenorphine maintenance
DRUG.00093	Sebelipase alfa (KANUMA™) No paid claims in most recent 12 months.	Criteria for lyposomal acid lipase deficiency (Wolman disease) in individuals less than 4 years-old and cholestryl-ester storage disease in individuals 4 and older with elevated liver enzymes.
CG-DRUG-59	Testosterone Injectable Replace Pharmacy PA criteria.	Criteria for symptomatic hypogonadism, delayed puberty, breast cancer, HIV associated wasting and transgender female-to-male reassignment.
DRUG.00091	Naltrexone Implants for the Treatment of Alcohol and Opioid Dependence	Investigational and not medically necessary criteria
DRUG.00015	Prevention of Respiratory Syncytial Virus Infections	Addition of proposed criteria for RI-002 (Ig supplementation) for individuals with primary immunodeficiency

DRUG.00024	Omalizumab (Xolair®)	Age criteria lowered to 6 years-old (from 12) for moderate to severe persistent asthma with elevated IgE
DRUG.00031	Subcutaneous Hormone Replacement Implants	Alignment with CG-DRUG-59 criteria for symptomatic hypogonadism, delayed puberty, and transgender female-to-male reassignment
DRUG.00042	Ustekinumab (Stelara®)	Minor changes to NMN statement
DRUG.00058	Pharmacotherapy for Hereditary Angioedema (HAE)	Lowered age limit for Berinert (C1 esterase inhibitor) from 13 to 5 y/o for acute HAE
CG-DRUG-11	Infertility Drugs	Removal of Repronex
CG-DRUG-21	Naltrexone (Vivitrol®) Injections for the Treatment of Alcohol and Opioid Dependence	Removal of oral naltrexone prerequisite