

**** Fee-For-Service Pharmacy Provider Notice #247 – September 2020 PDL Changes ****

November 6, 2020

Please be advised that the Department for Medicaid Services (DMS) is making changes to the Kentucky Medicaid Fee-For-Service (FFS) Pharmacy Preferred Drug List (PDL) based on recommendations and guidance as adopted by the Commissioner of the Department for Medicaid Services of the Cabinet for Health and Family Services by order dated October 9, 2020.

The Kentucky Medicaid FFS Pharmacy and Therapeutics Advisory Committee (Committee) met on September 17, 2020. A quorum was attained, allowing the expertise and votes were captured within the Committee’s official recommendations. DMS, through its Commissioner, reviewed the recommendations and in consultation rendered its final decisions.

On December 7, 2020 the following changes will be effective:

Existing Drug Classes

Drug Class	The following products will remain <i>preferred</i> products:	The following products will become <i>preferred</i> products:	The following products will become <i>non-preferred</i> products and require prior authorization (PA):	The following products will remain <i>non-preferred</i> products and require prior authorization (PA):
Alzheimer’s Agents	donepezil tablets (5 and 10 mg) Exelon® Patch memantine tablets rivastigmine capsules	donepezil ODT		Aricept® donepezil 23 mg Exelon® capsules galantamine galantamine ER memantine ER memantine solution Namzaric® Namenda® tablets Namenda XR® Razadyne® rivastigmine patch
Anticonvulsants: First Generation	Celontin® clobazam ^{QL} clonazepam tablets ^{QL} diazepam rectal gel ^{QL} divalproex delayed-release divalproex sodium ER divalproex sprinkle ethosuximide felbamate Peganone® phenobarbital ^{CC} phenytoin IR/ER primidone ^{CC} valproate valproic acid	Valtoco® ^{QL}		clonazepam ODT Depakene® Depakote® Depakote ER® Depakote® Sprinkle DiaStat® ^{QL} Dilantin® Felbatol® Klonopin® ^{QL} Mysoline® Nayzilam® ^{CC, QL} Onfi™ ^{QL} Phenytek® Sympazan™ ^{CC, QL} Zarontin®

Drug Class	The following products will remain <i>preferred</i> products:	The following products will become <i>preferred</i> products:	The following products will become <i>non-preferred</i> products and require prior authorization (PA):	The following products will remain <i>non-preferred</i> products and require prior authorization (PA):
Anticonvulsants: Second Generation	Banzel [®] CC, QL Gabitril [®] QL lamotrigine chewable tablets, tablets (except dose packs) levetiracetam ER ^{QL} levetiracetam solution, tablets ^{QL} Sabril [®] CC topiramate ^{QL} zonisamide ^{QL}		Xcopri [®] CC, QL	Briviact [®] QL Diacomit [™] CC, QL Epidiolex [™] CC Fycompa [™] QL Keppra [®] solution, tablets ^{QL} Keppra XR [®] QL Lamictal [®] Lamictal ODT [®] Lamictal [®] XR [™] QL lamotrigine dose packs lamotrigine ER ^{QL} lamotrigine ODT Qudexy [®] XR ^{QL} Spritam ^{QL} tiagabine ^{QL} Topamax [®] QL topiramate ER ^{QL} Trokendi XR [™] QL vigabatrin Vimpat [®] QL
Anticonvulsants: Carbamazepine Derivatives	carbamazepine tablets carbamazepine ER capsules (generic Carbatrol [®]) carbamazepine ER tablets Equetro [™] oxcarbazepine ^{QL} Tegretol [®] suspension			Aptiom [®] QL carbamazepine suspension Carbatrol [®] Epitol [®] Oxtellar [™] XR ^{QL} Tegretol [®] tablets Tegretol [®] XR Trileptal [®] QL
Antimigraine: CGRP Inhibitors	Emgality [™] 120 mg/mL CC, QL Nurtec [™] ODT CC, QL	Ajovy [™] CC, QL		Aimovig [™] QL Emgality [™] 100 mg/mL CC, QL Ubrelvy [™] CC, QL
Dopamine Receptor Agonists	bromocriptine pramipexole ropinirole			Mirapex [®] ER Neupro [®] Parlodel [®] pramipexole ER ropinirole ER
Parkinson's Disease	amantadine benztropine entacapone levodopa/carbidopa levodopa/carbidopa CR levodopa/carbidopa ODT selegiline trihexyphenidyl		Kynmobi [™] CC, QL	Azilect [®] carbidopa Comtan [®] Duopa [™] Gocovri [™] Inbrija [™] levodopa/carbidopa/entacaone Lodosyn [®] Nourianz [™] CC QL Osmolex [™] ER rasagiline

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				Rytary™ Sinemet® Sinemet® CR Stalevo® Tasmar® tolcapone Xadago® ^{CC, QL} Zelapar™
First-Generation Antipsychotics	amitriptyline/perphenazine chlorpromazine fluphenazine haloperidol loxapine perphenazine thioridazine thiothixene trifluoperazine			Adasuve® pimozone
Second-Generation Antipsychotics	aripiprazole tablets ^{CC, QL} clozapine tablets ^{CC, QL} Latuda® ^{CC, QL} olanzapine ^{CC, QL} quetiapine ^{CC, QL} quetiapine ER ^{CC, QL} risperidone ^{CC, QL} Saphris® ^{CC, QL} ziprasidone capsules ^{CC, QL}		Caplyta® ^{CC, QL}	Abilify® oral formulations ^{QL} aripiprazole ODT, oral solution clozapine ODT ^{QL} Clozaril® ^{QL} Fanapt™ ^{QL} FazaClo® ^{QL} Geodon® capsules ^{QL} Invega® ^{QL} olanzapine/fluoxetine ^{CC, QL} Nuplazid™ ^{QL} paliperidone ^{QL} Rexulti® ^{QL} Risperdal® ^{QL} Secuado® ^{QL} Seroquel® ^{QL} / Seroquel® XR ^{QL} Symbyax® ^{CC, QL} Versacloz® ^{QL} Vraylar™ ^{QL} Zyprexa® ^{QL}
Antipsychotics: Injectable	Abilify Maintena™ ^{CC, QL} fluphenazine decanoate ^{CC, QL} Geodon® injection ^{CC, QL} haloperidol decanoate ^{CC, QL} haloperidol lactate ^{CC, QL} Invega® Sustenna® ^{CC, QL} Invega Trinza™ ^{CC, QL} olanzapine ^{CC, QL} Risperdal® Consta® ^{CC, QL}			Aristada ER™ ^{QL} Aristada Initio™ ^{QL} Haldol® Decanoate ^{QL} Haldol® Lactate ^{QL} Perseris™ ziprasidone injection ^{QL} Zyprexa® ^{QL} Zyprexa® Relprevv ^{QL}

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Lipotropics: Bile Acid Sequestrants	cholestyramine cholestyramine light colestipol tablets Prevalite®			Colestid® colesevelam colestipol granules/packets Questran® Questran Light® WelChol®
Lipotropics: Other	ezetimibe omega-3 acid ethyl esters niacin ER		Nexleto™ ^{CC, QL} Nexlizet™ ^{CC, QL}	Juxtapid® Lovaza® Niaspan® Praluent® ^{CC} Repatha™ ^{CC} Vascepa® Zetia®
Lipotropics: Fibric Acid Derivatives	fenofibrate nanocrystallized (generic Tricor®) fenofibric acid (generic Trilipix®) gemfibrozil			Antara® fenofibrate Fenoglide® Lipofen® Lofibra® Lopid® TriCor® Triglide® Trilipix®
Neuropathic Pain	duloxetine DR (generic Cymbalta®) gabapentin capsules, solution, tablets ^{QL} pregabalin capsules ^{CC, QL}	lidocaine 5% patch ^{QL} pregabalin oral solution ^{CC, QL}		Cymbalta® DermacinRx PHN Pak™ duloxetine (generic Irenka™) Drizalma Sprinkle™ Gralise™ Horizant® Lidoderm® ^{QL} Lyrica® ^{QL} Lyrica® CR ^{QL} Neurontin® ^{QL} Savella® ZTlido™
Pulmonary Arterial Hypertension (PAH) Agents	ambrisentan ^{CC} sildenafil tablets ^{CC} Tracleer® tablets ^{CC} Ventavis® ^{CC}	tadalafil ^{CC, QL}		Adcirca™ Adempas® ^{CC} bosentan tablets Letairis™ Opsumit® Orenitram ER™ Revatio™ sildenafil suspension ^{CC} Tracleer® 32 mg tablets for suspension Tyvaso™ Upravi® ^{QL}

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Sedative Hypnotic Agents	flurazepam ^{MD, QL} temazepam 15 mg, 30 mg ^{MD, QL} triazolam ^{MD, QL} zolpidem ^{MD, QL}		Dayvigo ^{TM MD, QL}	Ambien ^{® MD, QL} Ambien CR ^{® MD, QL} Belsomra ^{® MD, QL} Doral ^{® MD, QL} Edluar ^{® CC, MD, QL} estazolam ^{MD, QL} eszopiclone ^{MD, QL} Halcion ^{® MD, QL} Hetlioz ^{® CC, QL} Intermezzo ^{® MD, QL} Lunesta ^{TM MD, QL} ramelteon ^{CC, MD, QL} Restoril ^{® MD, QL} Rozerem ^{® CC, MD, QL} Sonata ^{® MD, QL} temazepam 7.5 mg, 22.5 mg ^{MD, QL} zaleplon ^{MD, QL} zolpidem ER ^{MD, QL} Zolpimist ^{TM MD, QL}
Narcolepsy Agents	modafinil ^{CC, QL}			armodafinil ^{QL} Nuvigil ^{® QL} Provigil ^{® QL} Sunosi ^{TM CC, QL} Wakix ^{® CC, QL} Xyrem ^{® CC, QL} Xywav ^{® CC, QL}

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Stimulants and Related Agents	atomoxetine ^{CC, QL} dexamethylphenidate ^{CC, QL} Focalin XR [®] ^{CC, QL} guanfacine ER ^{CC, QL} methylphenidate solution ^{CC, QL} methylphenidate tablets ^{CC, QL} mixed amphetamine salts tablets ^{CC, QL} Vyvanse [®] capsules, chewable tablets ^{CC, QL}	Adderall XR [®] ^{CC, QL} Concerta [®] ^{CC, QL} Methylin [®] solution ^{CC, QL} methylphenidate solution ^{CC, QL}	Aptensio XR [®] ^{QL} Dyanavel [®] XR ^{QL} mixed amphetamine salts ER capsules ^{QL} QuilliChew ER [™] ^{QL} Quillivant XR [®] ^{QL}	Adderall [®] ^{QL} Adhansia XR [™] ^{QL} Adzenys ER [™] Adzenys XR-ODT [™] ^{QL} amphetamine ER suspension ^{QL} amphetamine sulfate clonidine ER ^{QL} Cotempla XR-ODT [™] ^{QL} Daytrana [®] ^{QL} Desoxyn [®] ^{QL} Dexedrine [®] ^{QL} dexamethylphenidate ER ^{QL} dextroamphetamine ER ^{QL} dextroamphetamine solution ^{QL} Evekeo [®] ^{QL} Evekeo [®] ODT ^{QL} Focalin [®] ^{QL} Intuniv [®] ^{QL} Jornay PM [™] ^{QL} Metadate [®] ER ^{QL} methamphetamine ^{QL} methylphenidate CD ^{QL} methylphenidate chewable tablets ^{QL} methylphenidate ER capsules, tablets ^{QL} methylphenidate ER OROS (generic Concerta [®]) ^{QL} methylphenidate LA ^{QL} Mydayis [™] ^{QL} ProCentra [®] ^{QL} Relexxii ^{QL} Ritalin [®] ^{QL} Ritalin LA [®] ^{QL} Strattera [®] ^{QL} Zenzedi [®] ^{QL}

Clinical Criteria

Clinical Criteria: Ajovy (and Emgality 120 mg/mL)

Criteria for Approval:

- Diagnosis of migraine with or without aura; AND
- If female of child-bearing age, negative pregnancy screening; AND
- Trial and failure (≥ 1 month) of at least 2 medications listed below from the 2012 American Academy of Neurology/American Headache Society guidelines – **at least 1 must be level A or B recommendation:**

Level A	Level B	Level C	
AEDs: <ul style="list-style-type: none"> • divalproex sodium • sodium valproate • topiramate 	Antidepressants: <ul style="list-style-type: none"> • amitriptyline • venlafaxine 	Alpha-agonists: <ul style="list-style-type: none"> • clonidine • guanfacine 	ACE/ARB: <ul style="list-style-type: none"> • lisinopril • candesartan
Beta blockers: <ul style="list-style-type: none"> • metoprolol • propranolol • timolol 	Beta blockers: <ul style="list-style-type: none"> • atenolol • nadolol 	AEDs: <ul style="list-style-type: none"> • carbamazepine 	Beta blockers: <ul style="list-style-type: none"> • nebivolol • pindolol
	NSAIDs: <ul style="list-style-type: none"> • fenoprofen • ibuprofen • ketoprofen • naproxen 	Antihistamines: <ul style="list-style-type: none"> • cyproheptadine 	NSAIDs: <ul style="list-style-type: none"> • flurbiprofen • mefenamic acid

AED = antiepileptic drug; ACE = angiotensin converting enzyme inhibitor; ARB = angiotensin receptor blocker; NSAIDs = nonsteroidal anti-inflammatory drugs

Renewal Criteria:

- Patient has an overall improvement in function with therapy (e.g., fewer and/or less severe migraine days per month); **AND**
- If female of child-bearing age, continued monitoring for pregnancy.

Clinical Criteria: Pulmonary Arterial Hypertension (PAH) Agents

Clinical criteria for will now apply for all preferred agents:

- Diagnosis of pulmonary hypertension (ICD-10 Disease Group = I27)

Consent Agenda

The therapeutic classes in the table below were reviewed; no changes were made to the currently posted status for agents in these classes.

- Angiotensin Modulator Combinations
- Angiotensin Modulators
- Antianginal & Anti-ischemic
- Antiarrhythmics, Oral
- Anticoagulants
- Antidepressants, Other
- Antidepressants, SSRIs
- Antidepressants, Tricyclic
- Antimigraine Agents, Triptans
- Anxiolytics
- Beta-Blockers
- Bladder Relaxant Preparations
- BPH Treatments
- Calcium Channel Blockers
- Lipotropics, Statins
- Movement Disorders
- Platelet Aggregation Inhibitors
- Skeletal Muscle Relaxants
- Smoking Cessation

New Products to Market

Drugs Requiring PA	Criteria for Prior Authorization
Xepi™	<p>Non-prefer with clinical criteria in the PDL class: <i>Antibiotics, Topical</i></p> <p>Length of Authorization: Date of service; no renewals</p> <ul style="list-style-type: none"> • Xepi™ (ozenoxacin) is a quinolone antimicrobial indicated for the topical treatment of impetigo due to Staphylococcus aureus or Streptococcus pyogenes in adult and pediatric patients 2 months of age and older. <p>Criteria for Approval:</p> <ul style="list-style-type: none"> • Diagnosis of impetigo; AND • Trial and failure with a preferred agent (e.g., mupirocin ointment); AND • Not have an affected body surface area (BSA) exceeding 100 cm² or 2% of total BSA, whichever is greater; AND • Will not be used for more than 5 days. <p>Quantity Limit: Up to 45 grams per fill</p>

Drugs Requiring PA	Criteria for Prior Authorization
Zeposia®	<p>Non-prefer in the PDL class: <i>Multiple Sclerosis Agents</i></p> <p>Length of Authorization: 1 year</p> <ul style="list-style-type: none"> • Zeposia® (ozanimod) is a sphingosine 1-phosphate (S1P) receptor modulator indicated for the treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults. <p>Criteria for Approval:</p> <ul style="list-style-type: none"> • Initially prescribed by a neurologist or multiple sclerosis specialist (non-specialist may renew and refill); AND • Patient has a diagnosis of a relapsing form of multiple sclerosis (MS): relapsing-remitting MS (RRMS) active secondary progressive MS (SPMS), or clinically isolated syndrome (CIS); AND • Patient has had an inadequate response to, or is unable to tolerate, 1 or more preferred MS agent; AND • Patient does NOT meet ANY of the following conditions: <ul style="list-style-type: none"> ○ Presence of contraindicated cardiovascular comorbidities (e.g., recent heart attack or stroke, heart failure); ○ Current systemic or clinically significant local infection; ○ Use of any other antineoplastic, immunosuppressive or immunomodulating drugs to treat other conditions; ○ Use of ozanimod in combination with another MS agent; ○ Prior use of alemtuzumab; AND • Patient has had or will have ALL of the following: <ul style="list-style-type: none"> ○ Screening for clinically significant drug interactions; AND ○ Baseline electrocardiogram (ECG), liver function tests (LFTs) and ophthalmic evaluation; AND ○ If pre-existing non-contraindicated cardiac disease (e.g., arrhythmia), cardiology consultation and follow-up will be conducted prior to and during treatment; AND ○ Testing for antibodies to the varicella zoster virus (VZV) OR have received immunization for VZV at least 4 to 6 weeks prior to beginning therapy. <p>Renewal Criteria</p> <ul style="list-style-type: none"> • Continue to meet initial approval criteria; AND • Documentation of response to therapy (e.g., progress note). <p>Age Limit: ≥ 18 years</p> <p>Quantity Limit: 1 per day</p>

Drugs Requiring PA	Criteria for Prior Authorization
Xcopri®	<p>Non-prefer in the PDL class: <i>Anticonvulsants: Second Generation</i></p> <p>Length of Authorization: 1 year</p> <ul style="list-style-type: none"> Xcopri® (cenobamate) is indicated for the treatment of partial-onset seizures in adult patients. <p>Criteria for Approval:</p> <ul style="list-style-type: none"> Diagnosis of partial-onset seizures; AND Trial and failure of a preferred agent; AND NOT have familial QT syndrome; AND NOT have severe hepatic impairment (Child-Pugh Class C). <p>Age Limit: ≥ 18 years</p> <p>Quantity Limit:</p> <ul style="list-style-type: none"> 1 per day: 50 mg, 100 mg tablets; titration blister packs 2 per day: 150 mg, 200 mg tablets; 250 and 350 mg maintenance blister packs
Kynmobi™	<p>Non-prefer in the PDL class: <i>Parkinson's Disease</i></p> <p>Length of Authorization: 1 year</p> <ul style="list-style-type: none"> Kynmobi™ (apomorphine) is a non-ergoline dopamine agonist indicated for the acute, intermittent treatment of "off" episodes in patients with Parkinson's disease (PD). <p>Criteria for Approval:</p> <ul style="list-style-type: none"> Diagnosis of Parkinson's disease (PD); AND Receiving PD therapy with carbidopa/levodopa; AND Experiencing "off" episodes with carbidopa/levodopa for at least 2 hours per day; AND Trial and failure of at least 2 adjunctive therapies, such as: <ul style="list-style-type: none"> Dopamine agonists (e.g., pramipexole, ropinirole); Monoamine oxidase-B inhibitors (e.g., selegiline) Catechol-O-methyltransferase inhibitors (e.g., entacapone); AND Patient will be offered a non-5HT3 antagonist antiemetic (e.g., trimethobenzamide); AND NONE of the following contraindications: <ul style="list-style-type: none"> Receiving concomitant 5-HT3 antagonists (e.g., ondansetron); OR Major psychiatric disorder. <p>Renewal Criteria:</p> <ul style="list-style-type: none"> Attestation or documentation (e.g., progress note) of a reduction in transfusion burden or other clinical benefit. <p>Age Limit: ≥ 18 years</p> <p>Quantity Limit: 5 per day</p>

Drugs Requiring PA	Criteria for Prior Authorization
<p>Caplyta®</p>	<p>Non-prefer in the PDL class: <i>Second-Generation Antipsychotics</i></p> <p>Length of Authorization: 1 year</p> <ul style="list-style-type: none"> Nourianz™ (istradefylline) is an adenosine A2A receptor antagonist approved as adjunctive treatment to levodopa/carbidopa (LD/CD) in adults with Parkinson’s disease (PD) experiencing “off” episodes. <p>Criteria for Approval:</p> <ul style="list-style-type: none"> Diagnosis of schizophrenia; AND Trial and failure of ≥ 2 preferred antipsychotics. <p>Renewal Criteria:</p> <ul style="list-style-type: none"> Attestation or documentation (e.g., progress note) of disease improvement and/or stabilization. <p>Age Limit: ≥ 18 years</p> <p>Quantity Limit: 1 per day</p>
<p>Nexleto™ and Nexlizet™</p>	<p>Non-prefer in the PDL class: <i>Lipotropics: Other</i></p> <p>Length of Authorization: 1 year</p> <ul style="list-style-type: none"> Nexleto™ (bempedoic acid) is an adenosine triphosphate-citrate lyase (ACL) inhibitor and Nexlizet™ (bempedoic acid/ezetimibe) contains an ACL inhibitor and a cholesterol absorption inhibitor. Both agents are indicated as an adjunct to diet and maximally tolerated statin therapy for the treatment of adults with heterozygous familial hypercholesterolemia (HeFH) or established atherosclerotic cardiovascular disease (ASCVD) who require additional lowering of low-density lipoprotein-cholesterol (LDL-C). <p>Criteria for Approval:</p> <ul style="list-style-type: none"> Prescribed initially by, or in consultation with a cardiologist, lipid specialist, endocrinologist, vascular medicine or other applicable specialist; AND Documentation of low-density lipoprotein cholesterol (LDL-C) prior to/without bempedoic acid therapy; AND Diagnosis of heterozygous familial hypercholesterolemia (HeFH) or established atherosclerotic cardiovascular disease; AND Trial and failure to achieve LDL goal after 3 months of high intensity statin therapy (e.g., rosuvastatin 40 mg daily); OR Patient does not tolerate statins (≥ 2 statin trials of any length were unsuccessful due to adverse effects); AND Maximum tolerated doses of lipid-lowering therapies (e.g., statin, ezetimibe, omega-3-acid ethyl esters) will continue to be used with bempedoic acid. <p>Renewal Criteria:</p> <ul style="list-style-type: none"> Documentation (e.g., progress note or lab report) that demonstrate a reduction in LDL-C when compared to the baseline values. <p>Age Limit: ≥ 18 years</p> <p>Quantity Limit: 1 per day</p>

Drugs Requiring PA	Criteria for Prior Authorization
Dayvigo™	<p>Non-prefer in the PDL class: <i>Sedative Hypnotics</i></p> <p>Length of Authorization: 30 days initial; 1year renewal</p> <ul style="list-style-type: none"> Dayvigo™ (lemborexant) is an orexin receptor antagonist indicated for the treatment of adult patients with insomnia, characterized by difficulties with sleep onset and/or sleep maintenance. It is a Schedule IV controlled substance. <p>Criteria for Approval</p> <ul style="list-style-type: none"> Diagnosis of insomnia; AND Trial and failure of ≥ 2 preferred sedative hypnotics. <p>Renewal Criteria</p> <ul style="list-style-type: none"> Attestation or documentation (e.g., progress note) of efficacy; AND Meets sedative hypnotic class criteria for therapy beyond 60 days. <p>Age Limit: ≥ 18 years</p> <p>Quantity Limit: 1 per day</p>

To review the complete summary of the final PDL selections and new products to market updates and changes, please refer to the “Commissioner’s Final Decisions” from September 17, 2020 posted on the provider web portal at: <https://kyportal.magellanhealth.com> (by clicking the Resources/Documents/Committees/P&T tabs).

Thank you for helping Kentucky Medicaid members maintain access to prescription coverage by selecting drugs on the preferred drug list whenever possible. Please contact Magellan Medicaid Administration at kyproviders@magellanhealth.com for any additional information or questions you may have.

Sincerely,

ShaLeigh Hammons

ShaLeigh Hammons, CPhT

Account Manager I

kyproviders@magellanhealth.com

Kentucky Medicaid Fee-for-Service Pharmacy Program's Contact Information		
Clinical Support Center	1-800-477-3071 Sunday – Saturday 24 hours a day	Please contact the Clinical Support Center to request a prior authorization (PA) or to check the status of a request.
Pharmacy Support Center	1-800-432-7005 Sunday – Saturday 24 hours a day	Please contact the Pharmacy Support Center when claims assistance is required. Timely filing, lock-in, and early refill (ER) overrides can be obtained through this Call Center.
Provider Services	1-877-838-5085 Monday – Friday 8:00 a.m. – 4:30 p.m.	Please contact Provider Services if you have questions about enrollment or when updating your license or bank information.
Member Services	1-800-635-2570 Monday – Friday 8:00 a.m. – 5:00 p.m.	Please contact Member Services if you are a member or if you as the provider have questions regarding the member's benefits or eligibility coverage dates.