January 18, 2013

Dear Kentucky Medicaid Provider:

Please be advised that the Department for Medicaid Services is making changes to the Kentucky Medicaid Preferred Drug List (PDL) based on recommendations from the Kentucky Medicaid Pharmacy & Therapeutics Advisory Committee at its November 15, 2012 meeting and as adopted by the Cabinet for Health and Family Services’ Commissioner by order dated December 14, 2012.

On February 20, 2013, the following changes will be effective:

- **New Drugs to Market**
  - The following product(s) will become non-preferred and require PA:
    - Dymista® (QL = 0.77 grams/day or 1 bottle per month)
    - Sklice™
    - Neupro®
    - Viokace™
    - Pertzye™
    - Myrbetriq™ (QL = 1/day)
    - Tudorza™ Pressair™ (QL = 1/month or .034/day)
    - Xtrand™ (QL = 4/day)
    - Bosulif® (QL = 1/day)

On February 26, 2013, the following changes will be effective:

- **Nucynta® ER Clinical Criteria**
  - Nucynta® ER will be authorized for the following diagnoses:
    - Pain after trial and failure of one preferred product; OR
    - Diabetic Peripheral Neuropathy after trial and failure of TWO of the following:
      - One SNRI; or
      - One anticonvulsant; or
      - One tricyclic antidepressant.

**Drug Class Changes**

- **First Generation Antipsychotics**
  - Amitriptyline/perphenazine, chlorpromazine, fluphenazine, haloperidol, loxapine, Moban®, Orap®, perphenazine, thioridazine, thiothixene, and trifluoperazine will remain preferred.
  - Loxitane® will remain non-preferred.
- **Second Generation Antipsychotics**
- Ability®, clozapine, clozapine ODT, Fanapt™, olanzapine, quetiapine, risperidone, Saphris®, Seroquel® XR, and ziprasidone will remain preferred.
- Lutada® will become preferred.
- Clozaril®, Geodon®, Invega®, Risperdal®, Seroquel®, and Zyprexa® will remain non-preferred.
- FazaClo® will become non-preferred.

**Second Generation Antipsychotics Clinical Criteria**

- Preferred Second-Generation Antipsychotics will be allowed for specific diagnoses only.
- Non-preferred Second-Generation Antipsychotics will be approved after a 2-week trial of ONE preferred Second-Generation Antipsychotic at an appropriate dose.
- Invega® will be approved if one of the following is true:
  - Trial and failure of risperidone; OR Patient has hepatic impairment evident by elevated liver enzymes or a diagnosis suggestive of hepatic impairment.
  - For a non-approvable diagnosis, a Second-Generation Antipsychotic may be approved if the prescriber can provide documented clinical evidence (peer reviewed literature or multiple case studies) supporting the use of the requested medication for the requested indication.

**Major Depressive Disorder (MDD) Criteria:**

- Second-Generation Antipsychotics will be approved for MDD as adjunct therapy ONLY.
- Second-Generation Antipsychotics will be approved if any ONE of the following is true:
  - An adequate trial (4 weeks) of at least one agent in two of the following classes of antidepressants (unless contraindicated or intolerant to):
    - Selective Serotonins Reuptake Inhibitor (SSRIs)
    - Serotonin-Norepinephrine Reuptake Inhibitor (SNRIs)
    - New Generation Antidepressants
    - Tricyclic antidepressants (TCAs); OR
    - A diagnosis of Major Depressive Disorder (MDD) with psychotic features.

**Multiple Agents Criteria:**

- Patients who are on more than 2 Second-Generation Antipsychotic agents will require PA. Approval will be granted for the following reasons:
  - A maximum of 2 months to allow patients to taper to dual therapy.
  - Additional agents may be added to existing dual therapy after a 2-week trial at the maximum tolerated dose of each agent.
  - Quantity Limits will be applied.

- Injectable Antipsychotics
  - Ability®, fluphenazine decanoate, Geodon®, haloperidol decanoate, Invega® Sustenna®, olanzapine, and Risperdal® Consta® will remain preferred.
  - Haldo® Decanoate, Zyprexa®, and Zyprexa® RelprevTM shall remain non-preferred.
multiple case studies) supporting the use of the requested medication for the requested indication.

**Multiple Therapy Criteria:**

- Patients who are on more than two Second-Generation Antipsychotic agents will require PA. Approval will be granted for the following reasons:
  - A maximum of 2 months to allow patients to taper to dual therapy.
  - Additional agents may be added to existing dual therapy after a 2-week trial at the maximum tolerated dose of each agent.
  - Quantity Limits will be applied.

- **Second Generation Antipsychotic and SSRI Combinations**
  - Symbyax® will remain **preferred**.
  - Olanzapine/fluoxetine will remain **non-preferred**.

- **Second Generation Antipsychotic and SSRI Combinations Clinical Criteria**
  - Olanzapine/fluoxetine will be approved if ONE of the following is true:
    - Diagnosis of depressive episodes associated with bipolar disorder after trial and failure of ONE of the following:
      - lithium; OR
      - lamotrigine; OR
      - bupropion; OR
      - paroxetine.
  - Diagnosis of treatment-resistant depression after trial and failure of one agent from THREE of the following classes of medications:
    - SSRI;
    - SNRI;
    - New Generation Antidepressant;
    - Tricyclic Antidepressant;
    - MAOI.
  - For a non-approvable diagnosis, olanzapine/fluoxetine may be approved if the prescriber can provide documented clinical evidence (peer reviewed literature or multiple case studies) supporting the use of the requested medication for the requested indication.

**Multiple Therapy Criteria:**

- Patients who are on more than 2 Second-Generation Antipsychotic agents will require PA. Approval will be granted for the following reasons:
  - A maximum of 2 months to allow patients to taper to dual therapy.
  - Additional agents may be added to existing dual therapy after a 2-week trial at the maximum tolerated dose of each agent.
  - Quantity Limit of 1 per day will be applied.

- **First Generation Anticonvulsants**
  - Celontin®, clonazepam, DiaStat®, divalproex delayed-release, divalproex sodium extended-release, ethosuximide, mephobarbital, Peganone®, phenobarbital®, Phenytek®, phenytoin ER, primidone, and valproic acid shall remain **preferred**.
  - Depakene®, Depakote®, Depakote ER®, diazepam rectal gel, Dilantin®, Klonopin®, Mysoline, Onfi™, Stavzor™, and Zarontin® shall remain **non-preferred**.
Second Generation Anticonvulsants
- Banzel®, felbamate, Gabitril®, gabapentin, lamotrigine, levetiracetam, Lyrica®, Sabril™, topiramate and zonisamide will remain preferred.
- Felbatol®, Keppra®, Keppra XR®, Lamictal™, levetiracetam XR, Neurontin®, Potiga™, Topamax®, Vimpat® and Zonegran® will remain non-preferred.
- Fanatrex™ and Gralise® will become non-preferred.

Banzel® Clinical Criteria
- Banzel® will be approved if:
  - Diagnosis of Lennox-Gastaut syndrome; OR
  - Trial and failure of one other anticonvulsant.

Lyrica® Clinical Criteria
- Lyrica® will be approved if any one of the following are true:
  - Diabetic Peripheral Neuropathy (DPN); OR
  - Postherpetic Neuralgia (PHN) AFTER adequate trial and failure of OR intolerance OR contraindication to at least one of these first-line agents
  - Tricyclic antidepressant (TCAs); or
  - Anticonvulsant: gabapentin; or
  - Topical: Lidocaine 5% patch.
  - Adjunct for partial onset seizure disorder; OR
  - Fibromyalgia.

Sabril™ Clinical Criteria
- Sabril™ will be approved if:
  - Diagnosis of infantile spasms; OR
  - Trial and failure of one other anticonvulsant.

Anticonvulsants, Carbamazepine Derivatives
- Carbatrol®, carbamazepine, carbamazepine XR, Equetro™ and oxcarbazepine will remain preferred.
- Carbamazepine extended-release (Generic for Carbatrol®), Tegretol®, Tegretol® XR, and Trileptal® will remain non-preferred and require PA.

On February 28, 2013, the following changes will be effective:

Stimulants and Related Agents
- Adderall XR®, dexamphetamine SR, dextroamphetamine ER, dextroamphetamine IR, Focalin XR®, Intuniv™, Metadate CD®, Metadate ER®, Methylphenidate, Methylphenidate Chewable®, methylphenidate IR, methylphenidate SA, methylphenidate SR, mixed amphetamine salts IR, Strattera®, and Vyvanse™ will remain preferred.
- Concerta® will become preferred.
- Adderall®, Daytrana®, Desoxyn®, Dexedrine®, Focalin®, Kapvay™, Methylphenidate solution®, methylphenidate (generic for Concerta®, Metadate CD®, Ritalin® LA), mixed amphetamine salts ER, modafinil, Nuvigil®, Provientra™, Provigil®, Ritalin®, Ritalin® LA, and Ritalin® SR will remain non-preferred.
- Methamphetamine will become non-preferred.

Stimulants and Related Agents Clinical Criteria
- Stimulants and Related Agents will be approved for specific diagnoses only.
- Agents may be approved for other diagnosis via the prior authorization process based on a review of the current literature by a clinical pharmacist.

AE - Age Edit; CC - Clinical Criteria; MD - Medications with Maximum Duration; QL - Quantity Limit; ST - Step Therapy
Daytrana™, Methylin® Solution, Methylin® Chewable Tabs, or Procentra™ will be approved if either of the following criteria is met:

- Trial and failure of two preferred products, one of which must be the same chemical as the requested medication; OR
- Inability to swallow/tolerate PO/whole tablets/capsules
  - For Daytrana™, inability to swallow/tolerate PO medications; OR
  - For Methylin® Solution, Methylin® Chewable Tabs, or Procentra™, inability to swallow tablets or capsules whole.

Therapeutic Duplication

- Prior authorization will be required for more than one long-acting (Adderall XR®, Concerta®, Daytrana™, Dexedrine®, dextroamphetamine ER, Metadate CD®, Metadate ER®, Focalin XR™, Methylin ER®, methylphenidate ER, methylphenidate ER OROS, methylphenidate SR, mixed amphetamine salt ER, Ritalin LA®, Ritalin SR®, Strattera®, Vyvanse®): OR
- More than one short-acting (Adderall®, Desoxyn®, dextroamphetamine IR, dextroamphetamine IR, DextroStat®, Focalin™, methamphetamine, Methylin®, methylphenidate IR, mixed amphetamine salt IR, Procentra™, Ritalin®) stimulant at a time.

- Strattera® Clinical Criteria
  - Strattera® (atomoxetine) will be approved if both of the following criteria are met:
    - Specific diagnoses only AND;
    - Any one of the following criteria:
      - Trial and failure of one preferred stimulant and related agent in the past 90 days; OR
      - History of substance abuse or diversion on the part of the patient or caregiver; OR
      - History of stimulant-induced weight loss after trial of two stimulants; OR
      - History of tic disorder, including Tourette’s; OR
      - Co-morbid mood or anxiety disorder.

- Provigil® / Nuvigil® Clinical Criteria
  - Provigil® (modafinil) / Nuvigil® (armodafinil) will be approved if both of the following criteria are met:
    - Specific diagnoses (via ICD-9 override) only; AND
    - For Nuvigil® (armodafinil) ONLY, trial and failure of Provigil® (modafinil)

- SSRIs
  - Citalopram, fluoxetine, fluoxetine ER, fluvoxamine, paroxetine and sertraline will remain preferred.
  - Viibryd® will become non-preferred.

- SNRIs
  - Savella™, venlafaxine, venlafaxine ER capsules will remain preferred.
  - Cymbalta®, Effexor®, Effexor XR®, Pristiq™, and venlafaxine ER tablets will remain non-preferred.

- Cymbalta® Clinical Criteria
Cymbalta® will be authorized for the following diagnoses:
- Depression/Major Depressive Disorder/Generalized Anxiety Disorder/Social Anxiety Disorder/Panic Disorder: Approval after trial and failure or intolerance or contraindication to one preferred SNRI.
- Diabetic peripheral neuropathic pain
- Fibromyalgia
- Chronic musculoskeletal pain: Approval after trial and failure of or intolerance or contraindication to one NSAID.

Please refer to Preferred Drug List (PDL) and the Maximum Quantity Limits List at https://kentucky.magellanmedicaid.com/Providers/DrugInfo.asp for additional information related to the medications mentioned in this notice.

* Please note: All dates are subject to change.

Thank you for helping Kentucky Medicaid members to maintain access to prescription coverage by selecting drugs on the preferred drug list whenever possible.

Sincerely,

Kasie Purvis
Provider Relations Manager

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