TEXAS MEDICAID VENDOR DRUG PROGRAM DRUG UTILIZATION REVIEW BOARD MEETING - RETROSPECTIVE DRUG USE PROPOSALS

Friday, April 28, 2023 http://www.txvendordrug.com/

REVISED CRITERIA

- 1. Aerosolized Agents Metered-Dose Inhalers (MDIs): Anti-Cholinergic Drugs
- 2. Aerosolized Agents Metered-Dose Inhalers (MDIs): Anti-Inflammatory Drugs
- 3. Aerosolized Agents Metered-Dose Inhalers (MDIs): Beta2 Adrenergic Drugs (Long-Acting)
- 4. Aerosolized Agents Metered-Dose Inhalers (MDIs): Beta2 Adrenergic Drugs (Short-Acting)
- Anti-Depressants, Oral (Other)
- 6. Anti-Depressants, Selective Serotonin Reuptake Inhibitors

REVISED CRITERIA: AEROSOLIZED AGENTS - METERED-DOSE INHALERS (MDIS): ANTI-CHOLINERGIC DRUGS

REVISED CRITERIA: AEROSOLIZED AGENTS - METERED-DOSE INHALERS (MDIS): ANTI-CHOLINERGIC DRUGS

- Removed statement about removal of Utibron Neohaler® (indacaterol/glycopyrrolate) and Seebri Neohaler® (glycopyrrolate) from market
 - Products have been removed from criteria set
- <u>Table 2. Maximum Recommended Adult Anticholinergic Metered-Dose</u> <u>Inhaler Daily Dose – Combination Therapy</u>
 - Added Breztri Aerosphere® (budesonide, glycopyrrolate, formoterol fumarate)
- <u>Table 4. Days' Supply for Anticholinergic Metered-Dose Inhaler Products Monotherapy</u>
 - Removed institutional only package sizes

REVISED CRITERIA: AEROSOLIZED AGENTS - METERED-DOSE INHALERS (MDIS): ANTI-CHOLINERGIC DRUGS

- <u>Table 5. Days' Supply for Anticholinergic Metered-Dose Inhaler Products –</u>
 <u>Combination Therapy</u>
 - Added package size and days' supply for Breztri Aerosphere® (budesonide, glycopyrrolate, formoterol fumarate)
- Table 6. Drug-Drug Interactions with Inhaled Combination Anticholinergics
 - Removed discontinued products
 - Updated drug interaction resource to Clinical Pharmacology
- References updated throughout criteria set

- Updated wording for Symbicort® (budesonide/formoterol) indication for ease of reading
- <u>Table 2. Maximum Adult Daily Recommended Doses for ICS as</u> <u>Combination Therapy for Asthma and COPD</u>
 - Updated column order
 - Added that generic formulations are available for Symbicort® (budesonide/ formoterol), Advair HFA® (fluticasone/ salmeterol), Advair Diskus® (fluticasone/ salmeterol), and Breo Ellipta® (fluticasone/ vilanterol)
 - Added Breztri Aerosphere® (budesonide/ glycopyrrolate/ formoterol fumarate)

- <u>Table 3. Maximum Recommended Pediatric Doses for ICS as</u> <u>Monotherapy in Asthma</u>
 - Added generic formulation for Flovent HFA® (fluticasone)
- <u>Table 4. Maximum Pediatric Recommended Doses for ICS as</u> <u>Combination Therapy for Asthma</u>
 - Added that generic formulations are available for Symbicort® (budesonide/ formoterol), Advair HFA® (fluticasone/ salmeterol), and Advair Diskus® (fluticasone/ salmeterol)

Duration of Therapy

- Updated information about combined formoterol and budesonide therapy for maintenance and rescue therapy for patients with asthma from the Global Strategy for Asthma Management and Prevention guidelines
- <u>Table 5. Days' Supply+ for Available ICS as Monotherapy When Maximum Doses are Utilized (Adults and Children)</u>
 - Updated product package sizes
 - Removed products that are available as institutional only packaging
 - Added Breztri Aerosphere® (budesonide/ glycopyrrolate/ formoterol fumarate)

Duplicative Therapy

Added updated guideline information

- Drug Interactions
 - Table 7. ICS Drug-Drug Interactions
 - Updated drug interaction resource to Clinical Pharmacology
 - References updated throughout criteria set

Revised criteria: Aerosolized Agents – Metered-dose Inhalers (MDIS): Beta2 Adrenergic Drugs (long-acting)

- Updated information about combined formoterol and budesonide therapy for maintenance and rescue therapy for patients with asthma from the Global Strategy for Asthma Management and Prevention guidelines
- Removed references to Utibron Neohaler® (indacaterol/glycopyrrolate),
 Seebri Neohaler® (glycopyrrolate), and Arcapta Neohaler®
 (indacaterol) as these products have been discontinued

- Table 2. LABA Maximum Daily Dosage Recommendations in Adults with Asthma and COPD: Combination Therapy
 - Updated column order
 - Added that generic formulations are available for Symbicort® (budesonide/ formoterol), Advair HFA® (fluticasone/ salmeterol), Advair Diskus® (fluticasone/ salmeterol), and Breo Ellipta® (fluticasone/ vilanterol)
 - Added Breztri Aerosphere® (budesonide/ glycopyrrolate/ formoterol fumarate)
- Removed references to indacaterol as no products are currently on the market

Duration of Therapy

- Updated guideline recommendations about the use of formoterol and budesonide as maintenance and rescue therapy for patients with asthma
- Added statement that long acting Beta₂ agonists (LABAs) should generally only be used for maintenance therapy, and removed paragraph detailing indication of maintenance therapy for each LABA

Duration of Therapy

- <u>Table 6. Days' Supply for Available Long-Acting Beta2-Adrenergic</u>
 <u>Metered Dose Inhalers (Adult and Pediatric Patients) Combination</u>
 <u>Therapy</u>
 - Removed pack sizes for institutional use only
 - Added Breztri Aerosphere® (budesonide/ glycopyrrolate/ formoterol fumarate)

Drug-Drug Interactions

- <u>Table 7. Key Drug-Drug Interactions for Inhaled LABAs and Combination Products</u>
 - Updated drug interaction resource to Clinical Pharmacology
- References Updated throughout criteria set

Revised criteria: Aerosolized Agents – Metered-Dose Inhalers (MDIS): Beta2 Adrenergic Drugs (Short-Acting)

Dosage

- <u>Table 1. Maximum Adult Daily Dose for Inhalational Beta₂-Adrenergic Agents</u> (<u>Short-Acting</u>) – <u>Monotherapy</u>
 - Updated column order
 - Removed ProAir HFA® (albuterol) as product has been discontinued
 - Added exercise induced bronchospasm (EIB) indication to table for albuterol products
- Removed references to ProAir HFA® (albuterol)
- Table 3. Maximum Recommended Pediatric Daily Dose for Inhalational

<u>Beta2-Adrenergic Agents (Short-Acting) – Monotherapy</u>

- Removed ProAir HFA® (albuterol) as product has been discontinued
- Added exercise induced bronchospasm (EIB) indication to table for albuterol products

Dosage

- <u>Table 4. Days' Supply for Available Short-Acting Beta₂-Adrenergic Agent</u>
 <u>Metered-Dose Inhalers (Adult and Pediatric Patients) Monotherapy</u>
 - Removed ProAir HFA® (albuterol) and updated with generic formulation
 - Removed institutional only package sizes

Drug-Drug Interactions

- <u>Table 6. Inhaled Short-Acting Beta2-Adrenergic Agents Drug-Drug Interactions</u>
 - Updated drug interaction resource to Clinical Pharmacology
- References Updated throughout criteria set

- <u>Table 1. Adult and Elderly Maximum Recommended Antidepressant</u> <u>Dosages (Monotherapy) - Tricyclic Antidepressants</u>
 - Removed brand name Elavil® (amitriptyline) as only generic is manufactured at this time
 - Updated amitriptyline dosing to indicate dosing should be divided throughout the day
 - Updated amoxapine dosing to reflect product labeling
 - Separated imipramine hydrochloride and imipramine pamoate for clarification of available formulations
 - Removed brand name Norpramin® (desipramine) as only generic is manufactured at this time
 - Updated protriptyline dosing to reflect product labeling

- Dosage
- <u>Table 2. Adult and Elderly Maximum Recommended Antidepressant</u>
 <u>Dosages (Monotherapy) Tetracyclic Antidepressants</u>
 - Removed maprotiline as product is no longer on the market
- <u>Table 3. Adult and Elderly Maximum Recommended Antidepressant Dosages (Monotherapy) Monoamine Oxidase Inhibitors</u>
 - Updated indication of phenelzine to reflect product labeling
 - Updated maximum dose of EMSAM® (selegiline) transdermal patch to reflect product labeling

- Dosage
- <u>Table 4. Adult and Elderly Maximum Recommended Antidepressant Dosages (Monotherapy) Serotonin and Norepinephrine Reuptake Inhibitors</u>
 - Removed brand name Khedezla® (desvenlafaxine) as product is no longer on the market
- <u>Table 6. Adult and Elderly Maximum Recommended Antidepressant Dosages (Monotherapy) Miscellaneous Agents</u>
 - Removed Oleptro (trazodone) as this formulation is no longer on the market

- <u>Table 8. Pediatric Maximum Recommended Antidepressant Drug Dosages</u> (<u>Monotherapy</u>) – <u>Tricyclic Antidepressants</u>
 - Updated amitriptyline dosing to reflect product labeling
 - Removed imipramine pamoate formulations, added language clarifying imipramine pamoate is not approved for pediatric use
- <u>Table 10. Pediatric Maximum Recommended Antidepressant Drug Dosages</u> (<u>Monotherapy</u>) – <u>Serotonin and Norepinephrine Reuptake Inhibitors</u>
 - Removed brand name Khedezla® (desvenlafaxine) as product is no longer on the market

- Renal Impairment
- <u>Table 13. Select non-SSRI Antidepressant Dosage Modifications in Renal Impairment Monoamine Oxidase Inhibitors</u>
 - Removed tranylcypromine to reflect product labeling
- Drug-Drug Interactions
- Table 16. Major Drug-Drug Interactions for Non-SSRI Antidepressant Drugs
 - Updated drug interaction resource to Clinical Pharmacology
- References Updated throughout criteria set

ANTI-DEPRESSANTS, SELECTIVE SEROTONIN REUPTAKE INHIBITORS

ANTI-DEPRESSANTS, SELECTIVE SEROTONIN REUPTAKE INHIBITORS

- Updated paragraph describing FDA approved indications of SSRIs to reflect product labeling
- <u>Table 1. Oral SSRI Medications Adult Maximum Recommended Dosages Monotherapy</u>
 - Added citalopram 30 mg capsule
 - Separated fluoxetine dosing by indication for ease of reading
 - Removed Pexeva® (paroxetine) 40 mg due to product no longer being on the market
 - Separated Paxil® (paroxetine) dosing based off maximum dosing and indications
 - Decreased maximum dose of Paxil CR® (paroxetine) to reflect available formulations

ANTI-DEPRESSANTS, SELECTIVE SEROTONIN REUPTAKE INHIBITORS

Dosage

- <u>Table 3. Recommended SSRI Antidepressant Drug Dosages for Pediatric Patients Monotherapy</u>
 - Updated column order
 - Added citalopram 30 mg capsules
 - Added major depressive disorder (MDD) and obsessive-compulsive disorder (OCD) dosing

Drug-Drug Interactions

- Table 6. Major Drug-Drug Interactions for SSRI Antidepressant Drugs 1
 - Updated drug interaction resource to Clinical Pharmacology
- References Updated throughout criteria set

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