

# CMS / Drugs / COPD Updates

Summer 2017



In October 2016 CMS released its Final Rule-also known as the "Mega Rule." The mega rule consists of a comprehensive update that span all areas of safety and health standards in nursing homes. The rule is to be rolled out in 3 phases, with the process ending in November 2019.

## Main Phase I (effective Nov 2016) Changes in F425-Pharmacy Services (483.45)

- ❖ Drug Regimen Review
  - The facility's medical director has been added to the list of persons who must receive notifications of all irregularities found by the consultant pharmacist (*MTS revised summary report to reflect notification*)
  - The facility must develop and maintain policies and procedures for the monthly drug regimen review that include timeframes by which the irregularities must be addressed

### Upcoming Changes in Phase 2 (November 2017)

- ❖ PRN psychotropic drugs limited to 14 days → may be renewed & extended by prescriber to continue with rationale for continued use documented in the patient's clinical record (no limit on how long renewal can be for)
- ❖ PRN antipsychotic cannot be renewed after 14 days unless the prescriber evaluates the resident for necessity & appropriateness of therapy
- ❖ Consultant Pharmacists must include review of the medical record as part of the drug regimen review process
- ❖ Revision for psychotropic drug definition to mean any drug that affects brain activities & mental processing & behaviors which includes but is not limited to antipsychotics, anxiolytics, hypnotics, antidepressants

### Upcoming Changes in Phase 2 & 3 (November 2018 - 2019)

- ❖ Development of an Infection Prevention & Control Program (IPCP)
  - ❖ Goal is to reduce microbial resistance & decrease the occurrence of MDR organisms with required development of a system of identifying, tracking, reporting, investigating and controlling infectious diseases
  - ❖ Develop written standards, policies & procedures for the program
  - ❖ Antibiotic stewardship program should include multi-disciplinary team and creating of antibiotic protocols and monitoring policies.
  - ❖ Designation of an Infection Preventionist (IP) & participation of the IP in the QAPI process

## Facts

- ❖ The Mega Rule release in 2016 is the most comprehensive update since 1991

## New Drugs

- Insulin degludec (**Tresiba**®)-3<sup>rd</sup> long-acting insulin, after Lantus & Levemir
  - Duration of action ~42 hours
  - Can be administered at anytime of the day
  - Common adverse effects: hypoglycemia, nasopharyngitis, headache & URI
- Lesinurad (**ZURAMPIC**®)-unique MOA; inhibits the function of transporter protein involved in uric acid resorption
  - Has indication for use in combination with xanthine-oxidase inhibitor
- Pimavanserin (**NUPLAZID**®)-atypical antipsychotic; targets 5HT<sub>2a</sub> receptors via agonist and antagonist activity at these receptors
  - Indication for hallucinations & delusions associated with Parkinson's Disease psychosis
  - 1<sup>st</sup> drug approved for this indication

# Chronic Obstructive Pulmonary Disease (COPD) Updates

## COPD GOLD Guidelines Updated in 2017

- ❖ Assessment- patients should undergo spirometry to determine the severity of airflow limitation, then be assessed by dyspnea- either by Medical Research Council Questionnaire (mMRC) or COPD Assessment Test (CAT). In addition, history of exacerbations should also be evaluated.
- ❖ Smoking cessation is key-no evidence for effectiveness of e-cigarettes as a smoking cessation aide
- ❖ Pharmacological treatment should be individualized
- ❖ Influenza & Pneumonia vaccination decrease incidence of lower respiratory infections

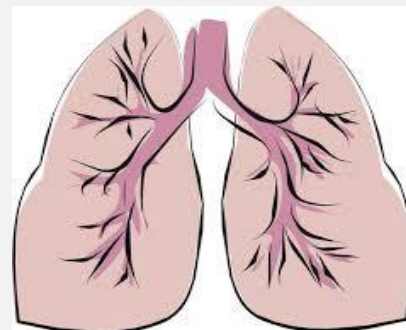
## COPD Facts

- ❖ 3<sup>rd</sup> leading cause of death in the US
- ❖ Main risk factor-smoking, other risk factors include: smoking, exposure to pollutants, underlying respiratory disorder, & genetic disorders
- ❖ Population >65 years old account for 35% of COPD population
- ❖ AMI, CHF, COPD, and pneumonia accounted for 13 percent of all readmissions, as well as 13 percent of aggregate hospital costs for readmissions in 2013.

## Treatment Caveats

- ❖ Tiotropium (Spiriva) improves the effectiveness of pulmonary rehabilitation in increasing exercise
- ❖ Long-Acting Anti-Muscarinics (LAMA) show greater improvement in reducing exacerbations & hospitalizations vs. Long-Acting Beta-2 Agonists
- ❖ Combination treatment (LABA+LAMA) superior to monotherapy
- ❖ Inhaled corticosteroids are associated with a higher prevalence of pneumonia, skin bruising, hoarse voice & candidiasis
- ❖ Long-term use of oral glucocorticoids has many side effects with no evidence of benefits
- ❖ Long-term use of antibiotics (azithromycin or erythromycin) show a reduction in exacerbations for up to a year, but do not come without risks of bacterial resistance

\*\*For video training on the technique of various inhalers, visit [use-inhalers.com](http://use-inhalers.com)



## New COPD Agents

- **Utibron Neohaler® (indacaterol + glycopyrrolate) → anticholinergic + long-acting B2-agonist**



- **Bevespi Aerosphere® (glycopyrrolate + formoterol) → anticholinergic + long-acting B2-agonist**

## DID YOU KNOW?

1. **There is no efficacy difference between nebulized agents and inhalers-as long as the technique is correct.**
2. **November is COPD Awareness month!**
3. **The majority of COPD expenditures are due to complications and hospitalizations, many of which are preventable**

## References:

2017 GOLD Guideline for COPD  
The Consultant Pharmacist May 2017, Volume 32  
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