CMS REGULATORY UPDATES 11.28.2017

F758 §483.45(c)(3) Psychotropic Drugs definition clarified to "any drug that affects brain activities associated with mental processes and behavior," including, but not limited to Anti-psychotic; Anti-depressant; Anti-anxiety; Hypnotic

F605 §483.12(a)(2) Freedom from Physical or Chemical Restraints

CMS recognizes the following psychiatric conditions as potentially requiring long-term medication use in the absence of ongoing symptoms to meet the clinical goal "to have no symptoms of the disorder."

- Chronic psychiatric illness such as schizophrenia or
  - schizoaffective disorder, bipolar disorder, depression, or post
  - traumatic stress disorder;
- Neurological illness such as Huntington's disease or Tourette's syndrome; and
- Psychosis and psychotic episodes.

Crucial to have required documentation: **"If the medication is still being used, the clinical record must reflect the rationale for the continued administration of the medication.** If no rationale is documented, this may meet the criteria for a chemical restraint. See page 117-122 for rationale requirements and examples for chemical restraints.
https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/GuidanceforLawsAndRegulations/Downloads/Advance-Appendix-PP-Including-Phase-2-.pdf

F693 §483.25(g)(4)-(5) Feeding Tube Regulation Changes

- CMS acknowledges that a feeding tube in advanced dementia "does not necessarily extend life."
- **Gastric residual volume checks no longer recommended for individuals who are able to report symptoms** that a feeding is not well tolerated (ex. bloating, nausea, or abdominal pain), but may be appropriate for individuals who are unable to report symptoms
- **"Auscultation is no longer recommended for checking placement of the feeding tube.** X-ray confirmation is the most accurate method *for verification of tube placement when concerns arise regarding dislodgement or placement.*"

F760 §483.*45(f)*(2) Free of any significant medication errors

- CMS now considers the simultaneous administration of phenytoin and enteral nutrition formula as a medication error.

F425 §483.45 Pharmacy Services - Psychotropic Drugs

- PRN psychotropic drugs (except antipsychotics) limited to 14 days unless longer use deemed appropriate by prescriber
- PRN antipsychotic drugs limited to 14 days and prescriber must reevaluate patient prior to renewal if there is continued need.

NEW DRUGS

- Plecanatide (**Trulance®**) –
  - MOA: guanylate cyclase-C agonist, increases intestinal fluid / accelerates GI transit
  - Indication: chronic idiopathic constipation
  - Can be given without regards to food
  - Same MOA as Linaclotide with similar efficacy

- Betrixaban (**Bevyxxa®**) –
  - MOA: inhibits clot formation through factor Xa inhibition
  - Indication: first and only anticoagulant for hospital and extended prophylaxis (35-45 days) of venous thromboembolism (VTE) in acutely ill patients at higher risk of VTE due to restricted mobility
  - Significant reduction in DVT / PE vs. enoxaparin WITHOUT a significant increase in major bleeding
  - 50% dose reduction with CrCl 15-30 mL/min

- *Tardive dyskinesia (TD)treatments:* MOA: reversible VMAT2 inhibition, downregulating dopamine release / decreasing stimulation of D2 receptors which lessons frequency / severity of TD

  Valbenazine(**Ingrezza®**) –

  - Indication: TD
  - Common adverse effect: Somnolence
  - Not recommended with CrCl <30 mL/min
  - QTc prolongation risk

  Deutetrabenazine (**Austedo®**)-

  - Indication: TD and chorea associated with Huntington's
  - Common adverse effect:
    - In TD: nasopharyngitis and insomnia
    - In Huntington's: sedation, diarrhea, dry mouth
  - QTc prolongation risk

NEW BP TARGET ANTICIPATED

- A new hypertension guideline from the American Heart Association and the American College of Cardiology will be published in November 2017. The new blood pressure goal is expected to be 130/80 mmHg for patients without diabetes.[2]
- According to results from the SPRINT trial, targeting a systolic blood pressure (SBP) < 120 mmHg was associated with a 25% lower risk of cardiovascular (CV) events and 43% lower relative risk of CV-related death when compared to targeting SBP < 140 mmHg after one year of targeting SBP < 120 mmHg[4]
- The SPRINT trial included patients over 50 years old, with hypertension and increased risk of CVD. The trial excluded patients with a history of a prior stroke or diabetes[4]

Heart Disease Facts

- 65% of Americans over the age of 60 have hypertension[7]
- Hypertension is associated with about 50% of ischemic strokes[6]
- Stroke, congestive heart failure, and coronary heart disease are three of the most common discharge diagnoses from hospitalizations in the year preceding the diagnosis of severe disability in the elderly[5]
- Heart disease is the leading cause of death in the United States in patients over age 65 years[1]

Treatment Caveats

- During the SPRINT trial on average one additional agent was needed to achieve SBP of 120 mmHg vs. 140 mmHg[4]
- Using an angiotensin converting enzyme inhibitor (ACEI)/angiotensin receptor blocker (ARB), thiazide diuretic, or calcium channel blocker (CCB) showed improved CV outcomes over α-blockers or β-blockers[3]
- CCBs and thiazide diuretics are preferred in African Americans without CKD due to better efficacy and decreased stroke rate, compared to ACEI/ARB[3]
- The more aggressive goal of an SBP of 120 mmHg is associated with an increase of syncope, electrolyte abnormalities, AKI, and hypotension, but has not been associated with a higher rate of serious adverse events, such as falls[5]

1. 10 Leading Causes of Death by Age Group, United States 2015. (2015). National Center for Injury Prevention and Control, CDC. www.cdc.gov/injury/wisqars/pdf/leading_causes_of_death_by_age_group_2015-a.pdf
2. Husten, L. (2017). *Upcoming US Guideline Will Likely Set 130/80 As New Blood Pressure Target*.
3. James PA, Oparil S, Carter BL et. al. 2014 evidence-based guideline for the management of high blood pressure in adults: report from the panel members appointed to the Eighth Joint National Committee (JNC 8). JAMA. 2014 Feb 5;311(5):507-20. doi: 10.1001/jama.2013.284427. Erratum in: JAMA. 2014 May 7;311(17):1809. PubMed PMID: 24352797.
4. SPRINT Research Group., A Randomized Trial of Intensive versus Standard Blood-Pressure Control. N Engl J Med. 2015 Nov 26;373(22):2103-16. doi: 10.1056/NEJMoa1511939. Epub 2015 Nov 9. PubMed PMID: 26551272; PubMed Central PMCID: PMC4689591.
5. Supiano MA, Williamson JD. Apply the Systolic Blood Presure Intervention Trial Results to Older Adults. J Am Geriatr Soc. 2017 Jan;65(1):16-21. doi: 10.1111/jgs.14681. Epub 2016 Nov 7. PubMed PMID: 28111758.
6. World Heart Federation. (2017). *Stroke and hypertension - World Heart Federation*. [online] Available at: https://www.world-heart-federation.org/resources/stroke-and-hypertension/
7. Cdc.gov. (2017). *High Blood Pressure Facts | cdc.gov*. [online] www.cdc.gov/bloodpressure/facts.htm

DEPRESCRIBING CONSIDERATIONS

Statins - In patients with poor prognosis/shortened life expectancy, there is minimal clinical benefit in continuing statin therapy; discontinuation has been shown to reduce costs and improve quality of life. [1] No adverse outcomes of stopping statins for primary prevention were found in 8 years after discontinuation[2]

Bisphosphonates - carry risk of atypical femoral fractures, osteonecrosis of the jaw, and esophageal cancer; Fracture risk reductions persist for years after the discontinuation[3]

Cholinesterase inhibitors - limited benefit in slowing Alzheimer's disease (AD) and carry risk of weight loss, nausea, vomiting, dizziness, fainting, muscle cramps, and bad dreams. Randomized, controlled trial found discontinuation safe and well-tolerated without clinical worsening in institutionalized patients with moderate to severe AD[4]

Vitamins/ Supplements - No significant benefit from multivitamins with minerals, folic acid, antioxidants, Vitamn C, B vitamins, and omega-3 fatty acids for prevention of mortality or morbidity due to chronic disease; some evidence of harm from β-carotene, vitamin E, and possibly high dose A; Vitamin D may be of limited benefit in the very elderly due to shortened life expectancy[5]

1.Kutner JS, et al. Safety and benefit of discontinuing statin therapy in the setting of advanced, life-limiting illness: a randomized clinical trial. JAMA Intern Med 2015;175(5):691-700.
2.Scott IA, et al. Reducing inappropriate polypharmacy: the process of deprescribing. JAMA Intern Med 2015; 175(5):827-834.
3. Black DM, et al. Effects of continuing or stopping alendronate after 5 years of treatment: the Fracture Intervention Trial Long-term Extension (FLEX): a randomized trial. JAMA. 2006;296(24):2927-38.
4.Hermann N. et al. J Am Med Dir Assoc. 2016 Feb;17(2):142-7. doi: 10.1016/j.jamda.2015.08.019.
5. Guallar E., et al. Enough Is Enough: Stop Wasting Money on Vitamin and Mineral Supplements. Ann Intern Med. 2013;159(12):850-851