



Indian Health Service
National Pharmacy and Therapeutics Committee
2018 NPTC Summer Meeting (UPDATE)
-August 2018-



The Indian Health Service (IHS) National Pharmacy and Therapeutics Committee (NPTC) held its summer meeting on July 31st and August 1st, 2018 in Rockville, MD. Eleven of the 12 IHS Areas were represented. W. Scott Butsch, MD, Director of Obesity Medicine at the Cleveland Clinic served as a subject matter expert and clinical speaker during the meeting. Affiliates from the Veterans Administration, Department of Defense, Federal Bureau of Prisons and Coast Guard provided information on formulary updates, clinical experiences and future meeting topics from their respective agencies. The NPTC values the relationships with its field experts, subject matter experts and federal partners and appreciates the opportunity to host the meeting from the IHS Headquarters Building.

The NPTC presentations consisted of comprehensive reviews of treatment(s) for Obesity, Seasonal Allergic Rhinitis, Pre-exposure Prophylaxis against HIV infection, and Opioid Use Disorder. A drug class review of Phosphodiesterase Type 5 Inhibitors was also provided.

The resulting action(s) from the meeting were as follows:

1. A therapeutic review of the Pharmacologic Treatment of Obesity was presented. Dr. Butsch was invited to serve as a subject matter expert and provided a comprehensive review of the topic with studies evaluating both past and present agents used for obesity. Agency procurement and utilization data combined with IHS pharmacoepidemiologic data from the National Data Warehouse (NDW) were also provided. After considerable discussion of available data supporting the use of the anti-obesity agents, the NPTC voted to **ADD phentermine** to the IHS National Core Formulary (NCF). Of note, there are several medications currently on the NCF (*e.g., bupropion, naltrexone, topiramate*) that have a role in the current practice of obesity treatment. As has become standard for all topics reviewed in NPTC meetings, a Formulary Brief will be authored and widely distributed with additional details that led to the NPTC decision.
2. A therapeutic review of Seasonal Allergic Rhinitis and guideline-recommended treatments was delivered to the NPTC. Drug classes as well as individual medications (within these drug classes) were critiqued. National and international guidelines served to guide the evaluation of current medications on the NCF. Available procurement, utilization, pharmacoepidemiologic and pharmacovigilance data from the National Supply Service Center and NDW were also included for NPTC review. Following the clinical and pharmacoeconomic reviews, **the NPTC made no formulary modifications to the current NCF**. A Formulary Brief detailing the individual medications addressed and key decisional information will be distributed shortly.
3. A drug class review of the Phosphodiesterase Type 5 (PDE5) Inhibitors was provided, covering the currently available agents (*avanafil, sildenafil, tadalafil, vardenafil*) used for erectile dysfunction. Clinical trials reviewed included both comparative and placebo-controlled reviews of the individual agents. A series of meta-analytic studies covering efficacy, safety and adherence were used to evaluate net benefit(s) and potential inclusion on the NCF. Following scrutiny of IHS utilization & procurement data along with available pharmacoepidemiologic data, the NPTC voted to **ADD any PDE5 Inhibitor** to the NCF. A NPTC Formulary Brief will be authored and disseminated shortly.

- 4. A therapeutic review of pharmacotherapy for Pre-exposure Prophylaxis (PrEP) against HIV infection was presented to and evaluated by the Committee. *Of note, tenofovir disoproxil fumarate/emtricitabine (Truvada®) was added to the NCF in 2009 specifically for occupational HIV post-exposure prophylaxis (oPEP) where it currently remains with the same guidance language.* Numerous organizational guidelines from the Centers for Disease Control and Prevention, World Health Organization and European AIDS Clinical Society were detailed along with meta-analyses of efficacy, safety and adherence. Agency procurement, utilization and pharmacoepidemiologic data were instrumental in providing added perspective. The NPTC ultimately voted to **ADD additional guidance language** to tenofovir disoproxil fumarate/emtricitabine (Truvada®) to include **“HIV pre-exposure prophylaxis (PrEP)”** to the current oPEP guidance language. A NPTC Formulary Brief will be authored and disseminated shortly.

- 5. A therapeutic review of Opioid Use Disorder (OUD) was provided, with specific focus on medication-assisted treatment for OUD. Of note, the NCF currently contains both naltrexone and naloxone without regard to indication or preferred route of administration. Each of the available MAT pharmacologic classes and individual medications (*buprenorphine, buprenorphine-naloxone, clonidine, lofexidine, methadone, and naltrexone*) were evaluated in detail, including reviews of studies comparing active and placebo controls. Multiple, recent Cochrane reviews and clinical practice guidelines, along with a review of the HHS Priority Areas, offered substantial value and guidance to the NPTC. Supplemental analyses from NDW and pharmaco-economic data added scope and insight on current use. Ultimately, the NPTC voted to **ADD (1.) buprenorphine-naloxone, (2.) naltrexone, oral and extended release for injection, and (3.) buprenorphine for treatment of OUD in pregnant patients, to the NCF.** A NPTC Formulary Brief will be authored and disseminated shortly.

***The next NPTC meeting will be the 2018 Fall (teleconference) Meeting, scheduled for November 1st, 2018. The agenda will include a review of Hepatitis C treatment guidelines and a drug class review of the available Hepatitis C medications.*

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