

INDIAN HEALTH SERVICE National Pharmacy & Therapeutics Committee **Fall 2021 NPTC Meeting Update**



=October 2021=

The Indian Health Service (IHS) National Pharmacy and Therapeutics Committee (NPTC) held its Fall 2021 virtual meeting on October 26-27, 2021. All 12 IHS Areas were represented. Agency subject matter experts providing consultation to the committee included Jonathan Iralu, MD (IHS Chief Clinical Consultant, Infectious Disease), Jean Howe, MD (IHS Chief Clinical Consultant, OB/GYN) and Andria Apostolou, PhD (Lead, IHS National STI Program). Affiliates from the Department of Defense, Veterans Administration, Coast Guard and Federal Bureau of Prisons provided information on formulary updates, clinical experiences, and 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 this virtual meeting through the Oklahoma City Area IHS Office.

The Fall 2021 Meeting agenda included clinical reviews and/or updates on (1) Antibiotic Stewardship and Upper Respiratory Infections, (2) Urinary Tract Infections, (3) Skin and Soft Tissue Infections, (4) Treatment Updates for Tuberculosis, (5) Guideline Updates for Sexually Transmitted Infections, and (6) Long-Acting Insulins and Biosimilars.

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

- 1. A therapeutic review of Outpatient Antibiotic Stewardship and Upper Respiratory Infections (URI) was delivered to the NPTC. Although azithromycin, ceftriaxone, doxycycline, and penicillin G benzathine are currently named to the National Core Formulary (NCF), their addition to the NCF followed a separate NPTC review of an unrelated health condition. Evidence provided during the evaluation included a review of antibiotic resistance and the CDC core elements of outpatient antibiotic stewardship. Focus was given to clinical guidelines and recommended therapies for otitis media, pharyngitis (viral and bacterial), sinusitis (viral and bacterial), and bronchitis specifically. Agency pharmacovigilance data and utilization/procurement trends added scope. Following review and deliberation, the NPTC voted to ADD both adult and pediatric oral formulations of the following: (1) amoxicillin, (2) amoxicillin and clavulanate, (3) cefdinir, (4) cephalexin, (5) clindamycin and (6) penicillin V potassium to the NCF.
- 2. A therapeutic review of <u>Urinary Tract Infections (UTIs)</u> was also delivered to the Committee. Although cefixime and ceftriaxone are currently named to the NCF and have indications for the treatment of UTIs, their addition to the NCF followed a separate NPTC review of an unrelated health condition. Guidelines and literature presented during this analysis included findings from the European Association of Urology, Infectious Diseases Society of America (IDSA), American Urological Association, National Institute of Clinical and Health Excellence (NICE), and multiple comparative randomized controlled trials (RCTs) and Cochrane Reviews. Relevant IHS pharmacoepidemiologic and pharmacoeconomic data were also presented. At the conclusion of the comprehensive analysis, the NPTC voted to <u>ADD nitrofurantoin</u> to the NCF.
- **3.** A therapeutic review of <u>Skin/Soft Tissue Infections (SSTIs)</u> was also provided to the NPTC. *Amoxicillin, amoxicillin and clavulanate, azithromycin, cefixime, ceftriaxone, cephalexin, clindamycin, doxycycline and penicillin G benzathine were all named to the NCF prior to this presentation, from separate NPTC reviews of unrelated health conditions. Decisional analyses from the Agency on Healthcare Research and Quality as well as practice guidelines from the*

IDSA, John Hopkins Antibiotic Guide and Sanford Antibiotic Guide were referenced. Data from the IHS National Data Warehouse (NDW) and Pharmaceutical Prime Vendor added perspective to the use of these therapies. Following the committee review, the NPTC voted to <u>ADD</u> (1) <u>mupirocin</u> and (2) <u>trimethoprim-sulfamethoxazole</u> to the NCF.

- 4. A therapeutic review of the <u>Treatment of Tuberculosis</u> (pulmonary and latent) was presented, with particular focus on recent published studies evaluating various pharmacotherapeutic strategies and treatment durations. *Ethambutol, isoniazid, pyrazinamide, rifampin and rifapentine are all currently listed on the NCF.* Clinical guidelines reviewed during the meeting included those from the American Thoracic Society, CDC, ISDA, World Health Organization, European Respiratory Society and NICE. Agency-level pharmacovigilance and drug utilization /trending data were presented and were notable. Ultimately, the NPTC made **no modifications to the NCF**.
- 5. A review of the 2021 CDC Treatment Guidelines for Sexually Transmitted Infections (STIs) was provided. Following the NPTC initial review of STIs (Spring 2021), azithromycin, ceftriaxone, cefixime, doxycycline, and penicillin G benzathine were all named to the NCF at that time. This clinical review focused on updated clinical guideline recommendations from the CDC for all STIs and addressed the remaining STIs not covered in the initial review. Pharmacoepidemiology data from the NDW paired with agency pharmacoeconomic trends were presented. As a result, the NPTC voted to ADD (1) metronidazole, (2) tinidazole, and (3) valacyclovir to the NCF.
- 6. Lastly, a drug class review of the Long-acting Insulins and Biosimilars was delivered to the NPTC. At present, insulin detemir is the sole long-acting insulin named to the NCF. The clinical review evaluated comparative data on the safety, efficacy, side effect profiles and outcomes between long-acting reference (parent) medications and their biosimilars. Important changes in nomenclature were detailed, notably the newer FDA "interchangeability" labeling for certain biosimilar products. Agency pharmacovigilance and pharmacoeconomic trend data were of substantial value to the Committee. The NPTC voted to ADD any "interchangeable" insulin glargine product (Semglee® or Lantus®) to the NCF.

^{*}The next NPTC meeting will be the Winter 2022 Meeting scheduled for February 15-16, 2022. The meeting agenda will include reviews of (1) Topical Wound Care Products, (2) Alcohol Use Disorder, (3) COVID-19 Treatment Guidelines, (4) Bipolar Disorder, and (5) Ocular Pharmaceuticals.